

This electronic thesis or dissertation has been downloaded from the King's Research Portal at <https://kclpure.kcl.ac.uk/portal/>



**Computerised decision support to aid primary care clinicians in the management of specialist drugs**  
**An evaluation of the needs of UK General Practitioners (GPs)**

Chana, Narinder Singh

*Awarding institution:*  
King's College London

The copyright of this thesis rests with the author and no quotation from it or information derived from it may be published without proper acknowledgement.

**END USER LICENCE AGREEMENT**



**Unless another licence is stated on the immediately following page** this work is licensed

under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International

licence. <https://creativecommons.org/licenses/by-nc-nd/4.0/>

You are free to copy, distribute and transmit the work

Under the following conditions:

- Attribution: You must attribute the work in the manner specified by the author (but not in any way that suggests that they endorse you or your use of the work).
- Non Commercial: You may not use this work for commercial purposes.
- No Derivative Works - You may not alter, transform, or build upon this work.

Any of these conditions can be waived if you receive permission from the author. Your fair dealings and other rights are in no way affected by the above.

**Take down policy**

If you believe that this document breaches copyright please contact [librarypure@kcl.ac.uk](mailto:librarypure@kcl.ac.uk) providing details, and we will remove access to the work immediately and investigate your claim.

**Computerised decision support  
to aid primary care clinicians in  
the management of specialist  
drugs: An evaluation of the  
needs of UK General  
Practitioners (GPs)**

**Submitted By  
Narinder Singh Chana**

**to Kings' College London as a  
thesis for the degree of  
Doctor of Healthcare**

In the UK since the early 1990s there has been a growing trend for certain hospital initiated specialist drugs to be prescribed by GPs within primary care. GPs have been encouraged to undertake this activity supported by the use of so-called “shared care protocols.” Despite these arrangements this has proven difficult with concerns over the quality and availability of shared care protocols and reported safety related incidents including fatalities linked to the use of certain specialist drugs.

GPs have benefited from the complete computerisation of general practice unlike their hospital based colleagues who on the whole continue to work and prescribe within paper-based systems. These benefits have included the use of electronic prescribing and the introduction of computerised decision support systems (CDSS) in the form of reminders and drug related warnings and alerts. Scoping reviews are an established way of assessing the evidence base of a subject area which can then be summarised to reflect the broad nature of the field. For this thesis a scoping review of CDSS was used to evaluate how this intervention has been used within primary care and to identify areas where it can be further developed. Although the use of information technology has been suggested as a possible solution to some of the problems at the primary and secondary care interface, no published studies have evaluated the potential for a CDSS to support the prescribing of specialist drugs by GPs.

In order to explore this concept further and gain additional knowledge of current CDSS usage, key informants were identified and interviewed. The key informants described the current availability and characteristics of CDSS within UK general practice. The concept of developing a CDSS to support GPs in the use of specialist drugs to include prescribing was acknowledged as beneficial and was widely supported. Enablers and barriers to development and implementation were identified including a number of potential operating models. Key enablers included data quality and functionality features, joint development and implementation and to make use of existing systems and frameworks. Key barriers included addressing the needs of end users, security, regulation and funding.

Human ergonomics was used to further investigate GPs and the actual level and use of computers and software programs including CDSS at the point of prescribing both during and outside of patient consultations. The application of an analytical approach to these processes through a task analysis framework identified failings in existing arrangements for GPs to safely prescribe specialist drugs.

Time constraints during patient consultations and the current lack of specific functionality within GP computer systems including CDSS adversely affected the ability for GPs to address issues at the primary and secondary care interface including the decision making process followed towards accepting clinical responsibility in prescribing specialist drugs.

A potential operating model for general practice to support GPs in the prescribing and use of specialist drugs has been identified. However a number of questions remain in terms of potential development and implementation. Government policy continues to drive secondary care services out into primary care and with this the possibility of even greater levels of specialist drugs being initiated and continued to be prescribed by GPs. This only adds a greater need and urgency for suppliers of information technology to include CDSS to provide solutions to clear safety concerns within the current arrangements for GPs and prescribing specialist drugs.

This thesis is dedicated to my late parents Mr Piara Singh Chana and  
Mrs Surjit Kaur Chana

When I embarked on the Doctorate in Healthcare I never envisaged the course of events that would come my way. To say it has been a journey would be an understatement. Over the years despite the ups and downs, I somehow felt an inner drive to keep going and work harder. For this I have to express sincere gratitude to my supervisors Dr Cate Whittlesea and Professor Brendan Delaney. It has been an absolute privilege working with them both and I will always be indebted to them.

I would like to thank the following staff from Kings' College London who have supported me with this thesis. Billy Wong and Tahee Choi for their wonderful training, support and advice in the use of NVIVO. I would also like to thank Talya Porat for helping and supporting me with understanding and applying both hierarchical task analysis and SHERPA error analysis techniques.

I am extremely grateful for the funding support towards the course fees for the Doctorate in Healthcare provided by Takeda Pharmaceuticals and Glaxo Smith Kline.

Last but not least, I would like to thank my whole family who have helped and supported me in so many ways throughout my time studying for this Doctorate; my wife Parvinder Kaur Chana, my sons Rajan Singh Chana, Roshan Singh Chana and my daughter Ramnik Kaur Chana. In addition, I would like to thank my oldest son Rajan Singh Chana for all his assistance and hard work in supporting the formatting and final preparation of this thesis.

When I was at primary school one of my favourite places to go to was the library in Osterley Park Road, Southall, Middlesex. What always intrigued me was the inscription on the stone floor as you entered this beautiful historic building, ***"Knowledge in Power."***

## Contents

<b>ABSTRACT .....</b>	<b>2</b>
<b>DEDICATION .....</b>	<b>4</b>
<b>ACKNOWLEDGEMENTS .....</b>	<b>5</b>
<b>TABLE OF CONTENTS .....</b>	<b>6</b>
<b>LIST OF TABLES .....</b>	<b>13</b>
<b>LIST OF FIGURES .....</b>	<b>15</b>
<b>LIST OF APPENDICIES .....</b>	<b>16</b>
<b>GLOSSARY OF TERMS .....</b>	<b>17</b>
<b>CHAPTER 1: THE QUALITY OF PRESCRIBING BY GENERAL PRACTITIONERS .....</b>	<b>19</b>
1.1 Thesis overview .....	20
1.2 Thesis aims and objectives.....	21
1.3 UK National drug expenditure.....	22
1.4 Regulation of medicines in the UK .....	23
1.5 The NHS and the role of GPs .....	23
1.6 Regulation of GP prescribing.....	24
1.7 Defining prescribing quality.....	25
1.7.1 Rational prescribing .....	26
1.7.2 The World Health Organisation .....	26
1.7.3 Prescribing indicators in the UK .....	30
1.7.4 Evidenced based medicine.....	32
1.7.5 Prescribing formularies: Historical perspectives .....	33
1.7.6 Developing hospital and primary care formularies.....	33
1.7.7 Financial incentives in prescribing and the GP contract.....	35
1.7.8 The Kings Fund: The quality of GP prescribing .....	37
1.8 Computers in UK general practice.....	38
1.9 Computerised decision support systems (CDSS).....	38
1.9.1 Rule based systems .....	40
1.9.2 Expert based systems .....	40
1.10 Discussion .....	41
<b>CHAPTER 2: COMPUTERISED DECISION SUPPORT SYSTEMS (CDSS): A SCOPING REVIEW .....</b>	<b>42</b>
2.1 Introduction.....	43
2.2 Scoping reviews .....	43

2.3 Methods.....	47
2.3.1 Identifying relevant studies .....	47
2.3.1.1 Healthcare database searches.....	49
2.3.1.2 Website reviews.....	50
2.3.1.3 Personal communication .....	50
2.3.2 Study election .....	51
2.3.3 Charting the data .....	51
2.4 Results.....	51
2.4.1 Systematic reviews .....	54
2.4.2 CDSS and international experience in primary care .....	61
2.4.3 CDSS and UK experience in primary care.....	63
2.4.3.1 CDSS UK end user evaluations .....	71
2.4.3.2 Safety deficiencies and overriding of CDSS alerts .....	72
2.4.3.3 CDSS and therapeutic blood monitoring.....	75
2.4.3.3.1 Primary care anticoagulation management .....	75
2.4.3.4 Other supporting literature.....	80
2.4.3.5 Website reviews.....	80
2.4.3.6 Personal communication.....	82
2.5 Discussion .....	82
2.6 Limitations .....	84
2.7 Further work .....	84
2.8 Conclusion.....	85
 <b>CHAPTER 3: AN EXPLORATORY STUDY USING KEY INFORMANTS TO INVESTIGATE THE USE OF COMPUTERISED DECISION SUPPORT SOFTWARE (CDSS) WITHIN UK GENERAL PRACTICE .....</b>	 <b>86</b>
3.1 Specialist drugs and shared care .....	87
3.1.1 Specialist drugs: Primary care prescribing trends .....	88
3.1.1.1 Data limitations .....	92
3.2 Organ transplantation .....	92
3.2.1 Immunosuppressant drugs.....	95
3.2.2 The national reporting learning service.....	95
3.2.3 Generic prescribing.....	97
3.3 Shared care protocols.....	99
3.4 Summary .....	102
3.5 Aims and objectives .....	102



3.6 Methods.....	103
3.6.1 Selection criteria .....	104
3.6.2 Interview schedules .....	104
3.6.3 Audio recording.....	105
3.6.4 Ethical approval .....	105
3.6.5 GP pilot .....	105
3.6.6 The interviews.....	105
3.6.7 Interview transcripts.....	106
3.6.8 Data analysis .....	106
3.6.9 Data quality analysis.....	107
3.7 Results.....	107
3.8 Primary themes .....	110
3.8.1 Safety .....	110
3.8.1.1 Communication .....	110
3.8.1.2 Clinical responsibility .....	111
3.8.1.3 Monitoring .....	111
3.8.1.4 Experiences of specialist drugs .....	112
3.8.1.4.1 Drug interactions.....	113
3.8.1.4.2 Generic prescribing.....	113
3.8.1.4.3 Repatriation.....	114
3.8.1.5 Shared care protocols .....	115
3.8.1.5.1 Development and approval of shared care protocols.....	115
3.8.1.5.2 Quality of shared care protocols.....	116
3.8.1.5.3 Acceptance of shared care protocols.....	117
3.8.1.5.4 Availability of shared care protocols.....	118
3.9 Information technology: Systems and functionality .....	119
3.9.1 Computer use in general practice .....	119
3.9.2 Key Characteristics of IT systems .....	120
3.9.2.1 Regulation .....	120
3.9.2.2 Hosted GP clinical systems .....	122
3.9.2.3 Data quality .....	123
3.9.2.3.1 Read coding.....	123
3.9.2.3.2 Accuracy .....	124
3.9.2.3.3 Accreditation .....	125
3.9.2.4 Integration of systems.....	126
3.9.2.5 Implementation of systems.....	127

3.9.2.5.1 Implementation of IT systems and the needs of end users.....	128
3.10 CDSS in primary care .....	129
3.10.1 Views and experiences of CDSS in primary care .....	134
3.10.1.1 GPs; views and experiences of CDSS.....	135
3.10.1.2 NHS IT managers' views and experiences of CDSS.....	136
3.10.1.3 CDSS informants' views and experiences of CDSS.....	137
3.10.2 Developments and improvements of CDSS in primary care .....	139
3.10.3 Specialist drugs and CDSS .....	139
3.10.3.1 Views of GPs .....	140
3.10.3.2 Views of CDSS informants .....	141
3.10.3.3 Views of NHS IT managers .....	142
3.10.3.4 Views of secondary care clinicians .....	143
3.11 Developing a novel CDSS to support the use of specialist drugs.....	144
3.11.1 Enablers.....	147
3.11.1.1 Multi-user access.....	147
3.11.1.2 Active alerts .....	148
3.11.1.3 Ease of use.....	149
3.11.1.4 Joint development and implementation.....	149
3.11.1.5 Patient involvement .....	150
3.11.1.6 Data quality and functionality .....	151
3.11.1.7 The use of existing systems and frameworks .....	153
3.11.2 Barriers.....	154
3.11.2.1 Integration and data quality .....	154
3.11.2.2 Security and Regulation .....	155
3.11.2.3 Implementation .....	156
3.11.2.4 Needs of end users.....	157
3.12 Costs .....	158
3.12.1 Drugs costs.....	158
3.12.2 Service costs.....	160
3.12.2.1 Homecare services.....	160
3.12.3 Funding of GP computers and IT systems.....	160
3.12.4 Funding models for CDSS and specialist drugs .....	162
3.12.4.1 Central funding .....	163
3.12.4.2 Extension of NHS funding arrangements.....	164
3.12.4.3 Other funding models .....	165
3.13 Discussion .....	167

3.13.1 Safety .....	167
3.13.2 Prescribing .....	167
3.13.2.1 Communication .....	168
3.13.2.2 Clinical responsibility .....	169
3.13.2.3 Monitoring .....	170
3.13.3 Experiences of specialist drugs .....	170
3.13.3.1 Drug interactions .....	170
3.13.3.2 Generic prescribing .....	171
3.13.3.3 Repatriation .....	172
3.14 Specialist drugs and shared care protocols .....	172
3.14.1 Attitudes and experiences of shared care protocols .....	172
3.14.2 Developing shared care protocols and their quality .....	173
3.14.3 Acceptance of shared care protocols .....	174
3.14.4 Awareness and availability .....	175
3.15 Information technology: Systems and functionality .....	175
3.15.1 Data quality and read coding .....	177
3.15.2 Accreditation .....	178
3.15.3 The views and experiences of CDSS in primary care .....	179
3.16 The views and experiences of CDSS in secondary care .....	181
3.17 Developments and improving CDSS .....	181
3.18 CDSS and specialist drugs .....	182
3.19 Costs .....	182
3.19.1 Drug expenditure .....	182
3.19.2 Funding of IT systems and CDSS .....	183
3.19.3 Commissioning of specialist services .....	184
3.20 Limitations .....	185
3.21 Further work .....	185
3.22 Conclusions .....	187

## **CHAPTER 4: TASK ANALYSIS OF THE USE OF COMPUTERS AND COMPUTING SOFTWARE BY GPS ..... 188**

4.1 Human factors and ergonomics .....	189
4.1.1 Error analysis techniques .....	191
4.1.2 Activity diagrams .....	192
4.2 Aims and objectives .....	192
4.3 Methods .....	193

4.3.1 Interview schedule .....	193
4.3.2 Selection criteria .....	194
4.4 Ethical approval.....	194
4.5 Results.....	195
4.5.1 Consultation .....	198
4.5.2 Use of GP computers .....	198
4.5.2.1 SystmOne .....	200
4.5.2.2 EMIS .....	200
4.5.2.3 Vision .....	200
4.5.3 Patient consultations.....	200
4.5.4 Recording templates and read coding .....	201
4.5.5 Prescribing .....	201
4.5.6 Referrals.....	202
4.5.7 Computer use outside of consultation .....	203
4.5.8 GMS contract and locally commissioned services.....	203
4.6 Case Scenario: Requests to prescribe specialist drugs .....	204
4.6.1 Prescribing specialist drugs.....	206
4.7 Hierarchical task analysis.....	206
4.7.1 SHERPA error analysis .....	207
4.7.2 Remedial strategies and design solutions.....	214
4.8 Discussion .....	216
4.9 Limitations .....	217
4.10 Further work .....	217
4.11 Conclusion.....	218
<b>CHAPTER 5: GENERAL CONCLUSION .....</b>	<b>219</b>
5.1 Overview.....	220
5.2 Scoping review .....	221
5.3 Key informant reviews.....	221
5.4 Task analysis.....	222
5.4.1 Extending the evidence base of CDSS .....	222
5.5 Limitations .....	224
5.6 Implications for clinical practice and policy .....	225
5.6.1 Implication for GPs .....	226
5.6.2 Implications for Clinical Commissioning Groups.....	226
5.6.3 Implications for CDSS suppliers .....	226

5.6.4 Enablers and barriers to implementation .....	226
5.7 Further work .....	227
5.8 Overall conclusion .....	228
<b>REFERENCES .....</b>	<b>229</b>
<b>APPENDICES .....</b>	<b>263</b>

**LIST OF TABLES**

<b>Table 1.1</b> Prescriptions dispensed in England during 2013 (HSCIC 2014).....	22
<b>Table 1.2</b> Rational prescribing indicators developed by the World Health Organisation (Hogerzeil 1995 p2) .....	27
<b>Table 1.3</b> Promoting the rational use of medicines by the World Health Organisation .....	28
<b>Table 1.4</b> Reliable indicators of prescribing appropriateness (Cantrill et al 1998). 30	
<b>Table 2.1</b> Key differences between systematic reviews and scoping reviews (adapted from Brian et al 2010) .....	44
<b>Table 2.2:</b> An overview of a methodological framework for conducting a scoping review (adapted from Arskey and O'Malley 2005).....	46
<b>Table 2.3</b> Methods used to obtain relevant studies and additional evidence .....	48
<b>Table 2.4</b> Results of healthcare database searches .....	49
<b>Table 2.5</b> Summary of website searches of commercial providers of CDSS .....	50
<b>Table 2.6</b> Characterisation of data identified from the scoping review of CDSS ...	53
<b>Table 2.7</b> Systematic reviews of CDSS.....	56
<b>Table 2.8</b> UK experience of CDSS within primary care settings.....	64
<b>Table 2.9</b> Studies have evaluated the safety of alerting systems provided by CDSS within GP clinical systems.....	73
<b>Table 2.10</b> UK studies of CDSS in anticoagulation management in general practice and the development of self-management. ....	77
<b>Table 2.11</b> Summary of the availability of CDSS from commercial providers in the UK.....	81
<b>Table 3.1</b> Top 30 Specialist rugs prescribed in primary care (GPs) by cost in England 2010 / 2011 .....	90
<b>Table 3.2</b> Top 30 Specialist drugs in primary care (GPs) by volume in England 2010 / 2011.....	90
<b>Table 3.3</b> Organ transplantations conducted in the UK by organ type 2008 – 2013 (adapted from NHS Blood and Transplant 2013) .....	94
<b>Table 3.4</b> Medication incidents involving ciclosporin, mycophenolate, sirolimus and tacrolimus by stage of medication process reported via the NRLS between 2005 – 2010 (NPSA 2011) .....	96
<b>Table 3.5</b> UK studies of shared care protocols .....	100
<b>Table 3.6</b> Profile summary of the 12 key informants.....	108
<b>Table 3.7</b> Summary of primary, secondary and sub-themes.....	109
<b>Table 3.8</b> Current profiles, usage and characteristics of CDSS available to use by GPs.....	130

<b>Table 3.9</b> Enablers and barriers for a CDSS to support the use of specialist drugs by key informant .....	146
<b>Table 3.10</b> Key functionality for a CDSS to support the use of specialist drugs ..	152
<b>Table 3.11</b> Funding models of a CDSS to support the use specialist drugs by key informant.....	163
<b>Table 4.1</b> Demographic characteristics of participating GPs .....	196
<b>Table 4.2</b> Hierarchical task analysis of the prescribing of specialist drugs by GPs. ....	207
<b>Table 4.3</b> SHERPA error modes .....	208
<b>Table 4.4</b> Application of SHERPA to the prescribing of specialist drugs by GPs.	209
<b>Table 4.5</b> Hierarchical task analysis of the prescribing of specialist drugs by GPs (Potential operating model supported by CDSS).....	215

**LIST OF FIGURES**

<b>Figure 1.1</b> Aims of good prescribing and their commonest conflicts (Barber 1995 p924).....	29
<b>Figure 2.1</b> Flow diagram of the steps followed during the scoping review.....	52
<b>Figure 3.1:</b> Quarterly prescribing rates and expenditure on all specialist drugs in primary care between 2006 / 07 and 2010 / 11 in England.....	89
<b>Figure 3.2:</b> Quarterly prescribing rates and expenditure for the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus in England between 2006 / 07 and 2010 / 11 .....	91
<b>Figure 3.3</b> The cost by pack of all oral formulations of tacrolimus, ciclosporin, sirolimus and mycophenolate available in the UK.....	98
<b>Figure 3.4</b> Summary of methods followed during this research study .....	106
<b>Figure 3.5</b> The views and experiences of the informants of shared care protocols by stakeholder group. ....	115
<b>Figure 3.6</b> The views and experiences of CDSS in primary care by stakeholder group .....	134
<b>Figure 3.7</b> The views and attitudes for a CDSS to support the use of specialist drugs by stakeholder group .....	140
<b>Figure 3.8</b> Enablers and barriers for a CDSS to support the use of specialist drugs by stakeholder group .....	145
<b>Figure 4.1</b> Activity diagram representing GPs' use of computers both during and outside of patient consultation. ....	199
<b>Figure 4.2</b> Activity diagram representing tasks involved in GPs' decision making in managing requests to prescribe specialist drugs .....	205



**LIST OF APPENDICES**

<b>Appendix 3.1</b> Interview Schedule: Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice. (GP Version) .....	263
<b>Appendix 3.2</b> Interview Schedule: Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice. (Secondary care clinician version).....	266
<b>Appendix 3.3</b> Interview schedule: Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice. (NHS management version) .....	269
<b>Appendix 3.4</b> Interview Schedule: Exploratory study to gather the views of key informants in relation to the use computerised decision support software (CDSS) within UK general practice (CDSS Stakeholder version) .....	272
<b>Appendix 3.5</b> Participant cover letter .....	275
<b>Appendix 3.6</b> Participant information leaflet.....	277
<b>Appendix 3.7</b> Participant consent form.....	280
<b>Appendix 3.8</b> Participant confirmation letter.....	281
<b>Appendix 4.1</b> Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice. Hierarchical Task Analysis (HTA): Researcher Guide .....	283
<b>Appendix 4.2</b> Participant information leaflet.....	285
<b>Appendix 4.3</b> Participant consent form.....	289

## Glossary of Terms

APC	Area Prescribing Committees
BMA	British Medical Association
BNF	British National Formulary
CCG	Clinical Commissioning Groups
CDSS	Computerised Decision Support Systems
CSD	Committee on Safety of Drugs
DH	Department of Health (DH)
DTC	Drugs and therapeutic committees
EMA	European Medicines Evaluation Agency
EMIS	Egton Medical Information Systems
HSCIC	Health and Social Care Information Centre
INPS	In Practice Systems
INR	International Normalised Ratio
GMS	General Medical Services Contract
GP	General Practitioner
GPSOC	GP Systems of Choice
MHRA	Medicines and Healthcare Products Regulatory Agency
NAO	National Audit Office
NICE	National Institute of Health and Clinical Excellence
NPC	National Prescribing Centre
NHS	National Health Service
NHS CFH	National Health Service Connecting for Health
PACT	Prescribing analysis and cost tabulation
EPACT	Electronic Prescribing analysis and cost tabulation
PPA	Prescription Pricing Authority
PPD	Prescription Pricing Division
PCGs	Primary Care Groups
PCTs	Primary Care Trusts

QOF	Quality and Outcomes Framework
RCT	Randomised Controlled Trial
WHO	World Health Organisation

# **Chapter 1**

## **The Quality of Prescribing by General Practitioners (GPs) in the UK**

## **1.1 Thesis overview**

The following chapters will explore the field of health informatics in relation to computerised decision support systems (CDSS) and opportunities to assess if and how CDSS can improve the quality of prescribing by GPs in the UK. Chapter 1 describes prescribing medicines by GPs in a historical context in order to provide insight to the evolution and establishment of regulatory frameworks and controls in the UK. With the national drugs bill signifying a large proportion of NHS expenditure various measures and interventions have been introduced from a regulatory perspective in order to contain costs by influencing prescribing behaviour (Britten 2001). Some of these interventions have allowed the development and use of a range of tools to measure prescribing and in specific areas have been used to introduce markers of prescribing quality. In addition background to these interventions is provided from a political and financial perspective in terms of NHS reforms. Defining prescribing quality is explored from a range of perspectives and stakeholders. Aspects of quality in prescribing are identified and improvements are discussed in relation to the better use of computers and health informatics including CDSS.

In Chapter 2, CDSS is further investigated in terms of primary care settings and use by GPs. A scoping review of the available literature in relation to CDSS was conducted using a range of sources of evidence. CDSS was found to be widely available within primary care settings with experience of use identified in a number of countries including the UK. Evidence from evaluations of CDSS was collated to include systems either being developed or in use and from the views and perceptions of end users. In addition the use of CDSS was identified in terms of supporting GPs in a range of clinical and therapeutic areas including prescribing. A key area identified where the use of CDSS was lacking was in supporting GPs in the use and prescribing of specialist drugs particularly with the use of shared care protocols.

Chapter 3 describes how the concept of developing a novel CDSS to support GPs in the use and prescribing of specialist drugs was explored in a research study that involved 12 participants representing key stakeholder groups including GPs, NHS IT managers, the CDSS industry and secondary care clinicians. The results of the study identified a number of potential operating models of a CDSS including enablers and barriers to support implementation.

Chapter 4 describes how this concept was further explored with a second research study involving nine GPs, who were users of three major GP clinical systems in the UK. This study involved an analytical examination of the way GPs actually used their computers and software applications both during and outside consultations. This analysis was used to further develop and build key operational functionalities to a potential CDSS that could support GPs in prescribing specialist drugs.

## **1.2 Thesis aims and objectives**

**Aim 1:** To identify from a scoping review the evidence base in relation to the use of CDSS by GPs in the UK.

### **Objectives**

- To assess the level and quality of evidence in relation to CDSS, to identify experience of use and areas or opportunities for CDSS to improving prescribing quality

**Aim 2:** To assess the feasibility of developing a CDSS to support GPs at the point of prescribing in the use and management of specialist drugs.

### **Objectives**

- To gain an understanding of current usage, system types and characteristics of CDSS within primary care.
- To build a practical understanding of current NHS management systems in relation to information technology, general practice and CDSS
- To explore how current financial constraints with the NHS may impact the delivery of CDSS in primary care
- To understand from commercial suppliers both historic, current and future strategy with regards to CDSS particularly in light of current NHS reforms
- To explore with secondary care clinicians the shared care protocol development process and the feasibility for incorporation into a CDSS for general practice

**Aim 3:** To identify an operating model for a potential CDSS to support GPs in the use of specialist drugs in order to ensure high level safety and quality in prescribing.

### Objectives

- To determine the actual level and use of computers and software applications including CDSS at the point of prescribing both during and outside of patient consultations by GPs
- To identify potential weakness or failings in existing systems that could be identified and be used in the development of a CDSS to support the use of specialist drugs.

### 1.3 UK national drug expenditure

Medicines are used in almost all NHS services making this the largest single expenditure in the NHS after staff costs (Picton 2008). Nationally the NHS spends around £12 billion on medicines with around 30% used in the hospital sector and the rest in primary care with the vast majority prescribed by General Practitioners (GPs). Figures provided by the Health and Social Care Information Centre (HSCIC) reported that in 2013 over 1 billion prescriptions were dispensed in England at a cost of £8.6 billion (HSCIC 2014). Table 1.1 summarises some of the statistics published by the HSCIC relating to prescriptions dispensed in the community in England during 2013.

**Table 1.1 Prescriptions dispensed in England during 2013 (HSCIC 2014)**

- |  |
|--|
| <ul style="list-style-type: none"><li>• 1,030,079 prescription items were dispensed at a total cost of £8,625,076</li><li>• The leading British National Formulary (BNF) chapter in terms of prescription items dispensed was the cardiovascular system (307,424) and in terms of net ingredient cost was the central nervous system (£1,878,279)</li><li>• The leading BNF section in terms of prescription items dispensed was hypertension and heart failure (68.7 million) and in terms of net ingredient cost was drugs used in diabetes (£793.8 million)</li><li>• 83.9% of all prescription items were prescribed as generic medicines</li><li>• The average net ingredient cost per head of population was £160.18 compared to £150.16 in 2003</li><li>• Exempt prescription items represented 90% per cent of all prescriptions dispensed</li></ul> |
|--|

#### **1.4 Regulation of medicines in the UK**

In 1957 the drug thalidomide was launched in Germany, as an over the counter medicine to promote sleep. The following year it became available in the UK as a prescription only medicine. At a paediatric conference in November 1961 it was reported that there was a possibility that, if taken in pregnancy, thalidomide might have harmful effects on the developing embryo (Rivett 2012). With increasing reports of adverse effects from around the world it became clear the drug was linked with causing abnormal birth defects. It is estimated that 10,000 babies were born with phocomelia and other deformities (Rago and Santoso 2008). In the UK the Government soon intervened and following consultation the Committee on Safety of Drugs (CSD) was formed in 1963 introducing a system of checking new drugs through three stages of assessment: laboratory toxicity trials, clinical trials on humans and post-marketing surveillance. With similar powers granted in the USA to the Federal Drug Agency (FDA) the thalidomide disaster also induced the process of harmonising drug regulation across the European Union through a number of Directives with the aim of creating a common market for medicines resulting in establishment of the European Medicines Evaluation Agency (EMA) in 1993 (Rago 2008). The CDS was renamed the Committee on Safety of Medicines (CSM) in 1970 and later the Commission on Human Medicines (CHM) advising the UK government on the safety, quality and efficacy of all medicines establishing the process of safety monitoring otherwise known as pharmacovigilance. The CHM is now one of eight expert groups that advise the Medicines and Healthcare Products Regulatory Agency (MHRA) which was formed in 2003. The MHRA is responsible for the regulation of all medicines, medical devices, equipment used in healthcare, and the investigation of harmful incidents.

#### **1.5 The NHS and the role of GPs.**

The 1911 National Health Insurance (NHI) Act consolidated existing contribution or insurance schemes placing all eligible working males on the panel of a named GP (Simon 2009). Under the Act, 80% of the working population of the UK were insured against sickness and debilitation and were able to receive a low sick payment that covered the cost of a doctor and prescribed medicine (Heller 2007). A capitation system of payment was introduced that meant income for GPs was related directly to the number of panel patients registered rather than the quality of medical care provided which eventually lead to a cap of 3000 panel patients per GP list in 1920 (Hardy 2001).



During the inter-war years the Labour party built up social welfare policies culminating in the 1942 Beveridge report, which first outlined the basis for a centrally funded welfare state to include a National Health Service or NHS (Laybourn 2000). Nye Bevan's NHS Act went much further than the Beveridge Report by proposing the nationalisation of hospitals and to draw GPs into the NHS on a partly salaried basis. Despite opposition internally from the Cabinet, the British Medical Association (BMA) and in particular hospital consultants, the NHS Act was passed in 1948 thus ensuring the original panel system was extended to cover the entire population of the UK. GPs acted as gate-keepers to the NHS, referring patients where appropriate to hospitals or specialist treatment and prescribing medicines and drugs.

### **1.6 Regulation of GP prescribing**

Concerns over escalating costs and prescribing patterns led to the Hinchcliffe Committee Inquiry which in its final report in 1959 recommended that expensive elegant preparations should give way to simpler preparations of the same drug, and doctors should be convinced of the superiority of a branded product before prescribing it rather than its generic equivalent (Rivet 2012). Following the Hinchcliffe Report arrangements were made to for the eight prescription pricing offices in England and Wales to obtain adequate statistical information about prescribing by analysis of samples of prescriptions submitted by community pharmacists. In addition prescribing data was collated quarterly and annually at both regional and national level to provide a means of drawing attention to specific patterns of prescribing of individual drugs or drug groups. By the early 1970s the availability of both educational and expenditure reports were supported by regional medical officers who would visit GPs annually with nearly 3,000 GPs specifically visited regarding the pattern and cost of their prescribing (Parish 1976). In 1977 the national pricing offices were renamed as the Prescription Pricing Authority (PPA) and reformed as a Special Health Authority. In 1988 the PPA overhauled its reporting format and introduced prescribing analysis and cost tabulation (PACT) data. Although traditionally PACT was mainly used as a financial tool to help health authorities set and monitor general practice prescribing budgets other purposes soon emerged such as audit and research, improved methods of funding high cost drugs, and the development of practice formularies and prescribing indicators (Majeed et al 1997).

The 1990 NHS and Community Care Act (Department of Health 1990) removed hospitals and community services from the managerial control of health authorities and allocated to them functions as either a "purchaser" or a "provider."

Providers could not rely on year on year funding, and in effect had to “compete” for contracts, and become more efficient and responsive to the needs of the purchaser. Fund holding allowed GPs to purchase health care from NHS trusts and the private sector, initially phased in with the first wave limited to those practices with list sizes in excess of 11,000. With successive waves of fund holding, allowing smaller practices to apply, the proportion of patients covered by fund-holding practices increased from 7% in 1991 to 51% by 1996 (Savage and Atkinson 2001).

The introduction of GP fund-holding and the internal market meant changes to both NHS district and regional management structures. This provided new strategic and operational opportunities for pharmacists to support GP fund-holders in prescribing management and started the concept of primary care pharmacy (Silcock et al 2003). Whilst fund-holding practices were allowed to overspend by up to 5% of their total spend (including prescribing), non-fund holding practices that overspent on prescribing were subject to possible sanctions ultimately resulting in the withholding of remuneration (Ryan and Yule 1993). By the end of the 1990s pharmaceutical advisers were employed by every Health Authority in England with others increasingly working directly for or within GP practices. The need for increasing levels of pharmaceutical support was in the main to control and manage an ever increasing national drugs bill. The primary care drugs bill in England had increased from £2.02 billion in 1989 to £5.2 billion by 1997 (Department of Health 2000). In 2003 the Audit Commission highlighted the sharp contrast between general drug inflation at 7% compared to 25% in areas linked to National Service Frameworks (NSFs) and guidance from the National Institute of Clinical Excellence (NICE); with the most significant factor driving the increases in drugs spending being the NSF for coronary heart disease (National Audit Office 2003). By 2007 the annual primary care drugs bill in England had reached £8 billion, an increase of 60% in real terms over the previous decade, with a 55% rise in the number of prescription items dispensed (National Audit Office 2007).

### **1.7 Defining Prescribing Quality**

In the UK the first reference to prescribing quality was suggested by Parish (1973), placing it in the context of a cash-limited health service as being appropriate, safe, effective and economic. Taylor (1977) described published studies at the time had focussed mainly on increasing drug expenditure whereas other perspectives reflecting the quality of prescribing were of a greater fundamental importance.

In this review the author banded the published literature into three categories; either using a descriptive approach based upon retrospective research of records, a deductive approach linking prescribing to morbidity or therapeutic intent, or from a qualitative perspective to examine personal influences on prescribing. Taylor (1977) concluded that without the support of continuous prescribing review systems as a basis of continuing education, GPs would have faced a greater degree of prescribing restriction.

### **1.7.1 Rational Prescribing**

Taylor (1978) in a second review of GP prescribing referred to a definition of rational prescribing based on the US Task Force on Prescription Drugs being “necessary, effective, safe and economic identifying both coercive and persuasive controls to improve GP prescribing.” Coercive controls were described as controls applied on manufacturers, prescribers and patients by external agencies, in essence Government regulation. Persuasive control was discussed in the context of postgraduate education, a wider use of approved publications e.g. the British National Formulary (BNF) and the use of detailed prescribing data. In contrast Bradley (1991) in a review of the published literature concluded that although the huge interest in escalating costs had led to initiatives that had curbed or altered prescribing it was the decision making process that underpinned prescribing and required a better understanding, particularly the decision to treat due to the lack of empirical evidence in this area.

### **1.7.2 The World Health Organisation**

In 1985 the World Health Organisation (WHO) formally defined requirements of rational prescribing as those required to meet the appropriate clinical needs of patients, at an appropriate dose for an appropriate period of time and at the lowest cost to them and their community (Le Grand et al 1999). Hogerzeil (1995) reported that in order to measure rational prescribing an adequate reference standard was required, as knowledge of rational drug use did not always result in rational prescribing behaviour. In the early 1990s the WHO in collaboration with the International Network of Rational Drug Use (INRUD) developed and tested 12 key quantitative indicators of rational prescribing and these are shown in Table 1.2.

**Table 1.2 Rational prescribing indicators developed by the World Health Organisation (Hogerzeil 1995 p2)**

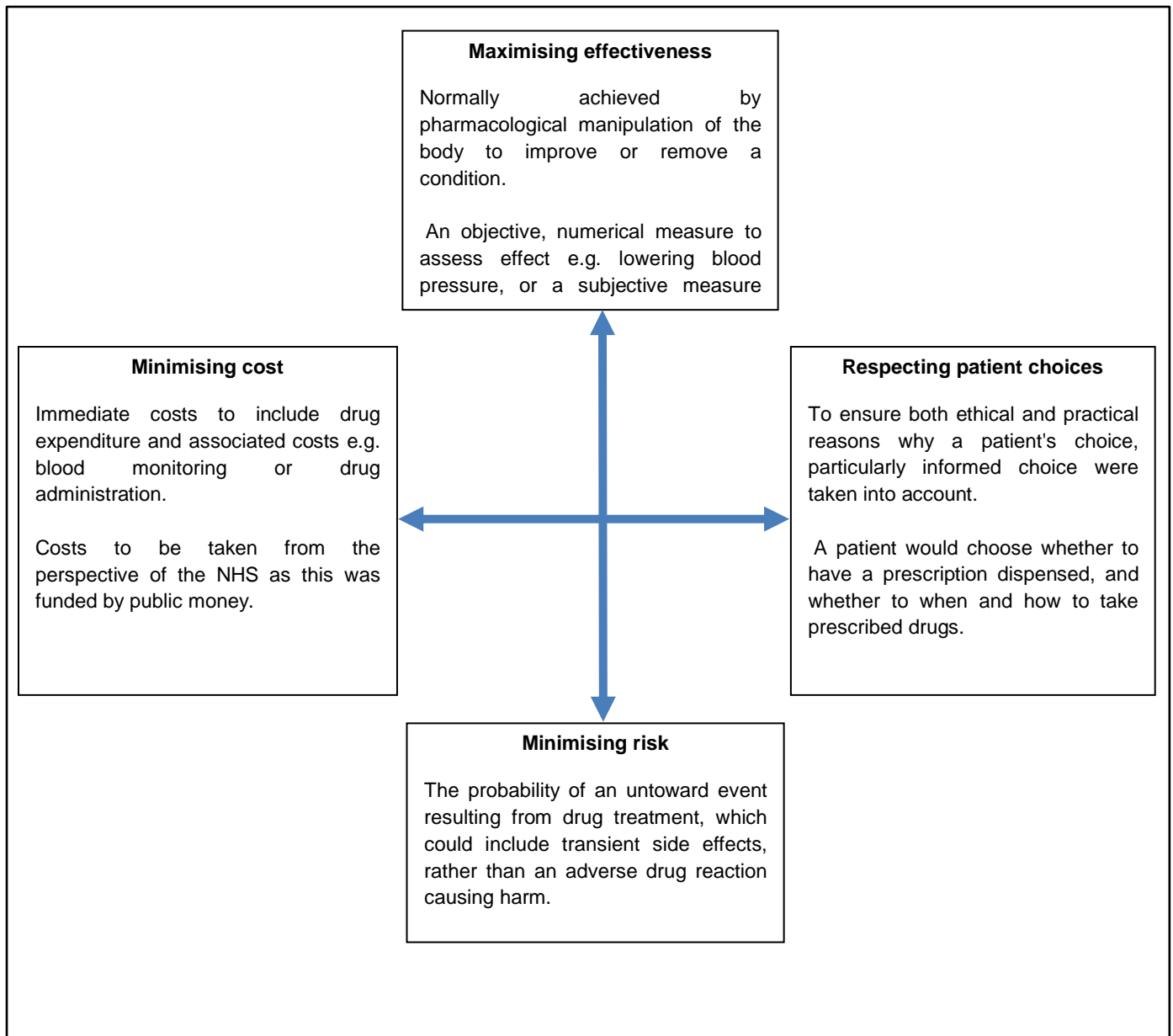
Prescribing Indicators
<ul style="list-style-type: none"><li>• Average number of drugs per encounter</li><li>• Percentage of drugs prescribed by generic name</li><li>• Percentage of encounters with an antibiotic prescribed</li><li>• Percentage of encounters with an injection prescribed</li><li>• Percentage of drugs prescribed from an essential drugs list or formulary</li></ul>
Patient Care Indicators
<ul style="list-style-type: none"><li>• Average consultation time</li><li>• Average dispensing time</li><li>• Percentage of drugs actually dispensed</li><li>• Percentage of drugs adequately labelled</li><li>• Patient knowledge of correct dosage</li></ul>
Facility Indicators
<ul style="list-style-type: none"><li>• Availability of a copy of essential drugs list or formulary</li><li>• Availability of key drugs</li></ul>

The World Health Organisation (WHO) continued to highlight the problems associated with irrational prescribing e.g. “poly-pharmacy” estimating that worldwide more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients failed to take them correctly and have recommended core interventions to combat irrational prescribing (World Health Organisation 2002). Table 1.3 describes how the WHO promoted the rational use of medicines.

**Table 1.3 Promoting the rational use of medicines by the World Health Organisation.**

- A mandated multi-disciplinary national body to coordinate medicine use policies
- Clinical guidelines
- Essential medicines list based on treatments of choice
- Drugs and therapeutics committees in districts and hospitals
- Problem-based pharmacotherapy training in undergraduate curricula
- Continuing in-service medical education as a licensure requirement
- Supervision, audit and feedback
- Independent information on medicines
- Public education about medicines
- Avoidance of perverse financial incentives
- Appropriate and enforced regulation
- Sufficient government expenditure to ensure availability of medicines and staff

With UK national annual prescribing costs in excess of £3 billion, Barber (1995) suggested an overhaul of the definition of rational prescribing by highlighting flaws in previous studies particularly where authors were mainly academic clinical pharmacologists. In addition the author added that in these cases prescribing quality was assessed against the biomedical model, balancing effectiveness of treatment against risk. Barber (1995) suggested a new definition of rational prescribing based on the premise that it was better to define what a good prescriber should be trying to achieve at the time of prescribing and subsequent management through four aims; to maximise effectiveness, to minimise risk; to minimise cost and to respect patient choice. Figure 1.1 shows how the author represented these four aims diagrammatically, plotting their commonest conflicts which could be used as an aid to discussion and decision making.



**Figure 1.1 Aims of good prescribing and their commonest conflicts**  
**(Barber 1995 p924)**

In 1996 the Department of Health launched the National Prescribing Centre (NPC) to facilitate the promotion of high quality and cost effective prescribing through a programme of activities aimed at supporting all relevant health professionals and managers in NHS (Simister 2000). The NPC based their working definition of prescribing quality in conjunction with both Barber and the WHO as a balance of the traditional teaching of safety and efficacy with the need to be cost-effective and involving the patient in treatment (National Prescribing Centre 2007a).

### 1.7.3 Prescribing Indicators in the UK

Bateman et al (1996) convened a consensus group consisting of 8 GPs and a resource team to develop, define criteria and set standards of prescribing performance using PACT data and then applied these to all 518 practices in the former Northern Regional Health Authority. The group developed criteria and set numeric standards for thirteen aspects of prescribing performance in four areas: generic prescribing, prescribing within specific therapeutic groups, drugs of limited clinical value and standards based on prescribing volume. Cantrill et al (1998) on behalf of the National Primary Care Research Centre (NPCRC) developed a set of 9 prescribing indicators combining both measures of appropriate and inappropriate prescribing including non-PACT indicators (see Table 1.4). The authors concluded that despite being too labour intensive for routine use these prescribing indicators were useful as a research tool and that with developments with information technology would increase wider accessibility.

**Table 1.4 Reliable Indicators of Prescribing Appropriateness (Cantrill et al 1998)**

- The indication for the drug is recorded and upheld in the BNF
- The reason for prescribing a drug of limited value is recorded an valid
- Compared with alternative treatments in the same therapeutic class , which are just as effective, the drug prescribed is either one of the cheapest or a valid reason is given for using alternative
- A generic product is used if one is available
- If a potentially hazardous drug-drug combination is prescribed, the prescriber shows knowledge of the hazard
- If the total daily dose is outside the range stated in the BNF, the prescriber gives a valid reason
- If the dosing frequency is outside the range stated in the BNF, the prescriber gives a valid reason
- If the duration of treatment is outside the ranges stated in the BNF, the prescriber gives a valid reason
- Prescribing for hypertension adheres to the evidenced based guidelines in the BNF

Avery (1998) reported that although over 400 prescribing indicators had been developed by various groups and organisations in the UK, including Health Authorities, many were not as robust as others in expressing the appropriateness of prescribing. Campbell et al (2000) used a modified two round Delphi questionnaire sent to all medical and pharmaceutical advisers in England (n = 305) to face validate 31 indicators in current use. From 79 respondents (26%) only 12 of the 31 indicators were rated as valid for either cost or quality perspectives. This suggested limitations in terms of application. Avery (1998) suggested that although prescribing indicators required further evaluation as to what they were trying to measure, they all had potential for development and could be incorporated into GP clinical systems as computerised prompts to encourage appropriate prescribing.

Limitations with PACT data, and in particular prescribing indicators, have been attributed to the lack of clinical information such as diagnosis and other patient specific denominators (Lloyd 2001). Guptha et al (2003) could only apply 9 out of 14 hospital derived indicators to an elderly population in the community and described primary care based prescribing indicators as inaccurate as they were based on overall prescribing and lacked patient clinical data. Key requirements for the development of prescribing indicators for use in the NHS is the need for them to be based on scientific evidence supplemented by expert advice and represent clinical areas regarded as important by clinicians and also in line with national health policies (Kendall 2004).

NHS reforms over recent years have seen huge increases in funding but with it a target driven and performance management framework across the whole NHS. Initiatives such as primary care benchmarking schemes or scorecards were introduced in order to measure GP practices against a range of performance targets that included prescribing indicators based on PACT data (Primary Care Contracting 2006). In 2006 the NHS Institute for Innovation and Improvement introduced three "Better Care Better Value" prescribing indicators to nationally benchmark all PCTs against the top quartile of performing organisations. In response to financial challenges, the Department of Health established quality, innovation, productivity and prevention (QIPP) as the guiding principles to help the NHS deliver its quality and efficiency commitments (Department of Health 2009b).



The QIPP medicines use and procurement criteria developed by key stakeholders, including the National Prescribing Centre, aimed to ensure that value for money was further enhanced whilst maintaining or improving quality of care by optimising the use of medicines. In order to support QIPP the continued use of prescribing indicators were central to measure and identify a range of prescribing initiatives and key therapeutic areas for implementation by local medicines management teams (National Prescribing Centre 2012).

#### **1.7.4 Evidenced Based Medicine**

Historically the formal assessment of medical interventions has principally been based around the evidence obtained from clinical trials. During the 1980s the concept of evidenced based medicine emerged, challenging this formal process and introducing a more practical methodology of assessment. Evidenced based medicine has been defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al 1996 p71). The basic principle of evidenced based medicine has been described as to treat where there is evidence of benefit and not to treat where there is evidence of no benefit (or harm), and that is of relevance at all levels of the NHS both strategically, tactically and individually (Besley 2009). The practice of evidenced based medicine involves integrating individual clinical expertise with the best available external clinical evidence from systematic research. Stephens (2005) has described a range of tiered hierarchy approaches to ranking evidence from the most reliable evidence to the least based on the design or nature of the source. The most reliable sources being systematic reviews including meta-analysis of randomised controlled trials and the least from sources such as expert opinion or case studies.

In the UK delivering evidenced based recommendations on medical interventions including drugs at a national level is the responsibility of the National Institute of Health and Clinical Excellence (NICE). Launched in 1999 as a Special Health Authority, the Institute aimed to produce and disseminate clinical guidelines on the relevant evidence of clinical cost effectiveness, associated audit methodology and information on good practice (Stephens 2005). In addition having a national body to assess new technologies overcame the previous often chaotic approach that led to postcode prescribing. Using a six-tiered approach to review evidence, recommendations, standards and services were developed in consultation with independent committees and experts. In addition NICE commissioned independent academic centres to review the published evidence on the relevant technology.

Granby (2005) has described the need for a structured approach to prescribing taking into account the efficacy and cost-effectiveness of treatment options, how to check the evidence, the benefits or harms of a treatment and, the patient's own involvement in the treatment plan. In contrast inappropriate and non-evidence-based prescribing can be detrimental, harming patients through side effects, adverse drug reactions, hospital admission and in some cases fatality.

#### **1.7.5 Prescribing formularies: Historical perspectives**

In 1864 the newly created General Medical Council (GMC) was authorised to prepare the British Pharmacopoeia, which for the first time in the UK laid down legally enforced standards for the quality individual drugs used in medicines (Wade 2003). In 1927 the British Medical Association (BMA) and the then Retail Pharmacist Association (now National Pharmaceutical Association) developed the first national medicines formulary containing 295 monographs (Thomson 2007). With the launch of the NHS in 1948 both the BMA and the Pharmaceutical Society of Great Britain (PSGB) worked together through a Joint Formulary Committee (JFC) leading to the publication of the first British National Formulary (BNF) in 1949. The following years saw the JFC implement periodical changes to content and design as new drugs and formulations became available. However with concerns growing over the influence of the Pharmaceutical Industry on doctors, during the mid-1970s the JFC were instructed to produce a BNF with much greater level of detail on all medicines available, drug prices and also of a size that would fit in a coat pocket (Wade 2003). Often described as the therapeutic bible, the BNF is considered by many as essential for clinical practice, bringing together authoritative and independent guidance on best practice with clinically validated drug information, enabling healthcare professionals to select safe and effective medicines for individual patients (Britton 2009).

#### **1.7.6 Developing hospital and primary care formularies**

Historically formularies have their origins in secondary care and were originally produced to encourage hospital doctors to prescribe from the selection of drugs contained therein (Furness 2000). Over time hospital formularies have changed to accommodate advances in medical practice, newer drugs and the wider availability of associated prescribing information. Modern hospital drug formularies are source of detailed local prescribing information incorporating treatment guidelines and summaries of best practice (Khan 2002). Central to formulary management process was the role of local drugs and therapeutic committees (DTCs).

Stephens (2005) described the evolution of DTCs in the UK since the 1970s and their original format of “hospital pharmacy committees” with GPs included in a minority capacity. Burrill (2003) reported on the response of former Health Authorities to a direction from the Department of Health {EL(94)72} that required appropriate action was taken on hospital-led prescribing and new drugs that led to the formation of area prescribing committees (APCs). Stephens (2005) described a growing frustration in terms of inequitable access to medicines and the emergence of APCs such as the Midland Therapeutic Review and Advisory Committee (MTRAC) as an attempt to deal with these pressures. A national survey of 77 APCs in England resulted in the publication of a national guide to good practice including advice on the drug recommendation process (National Prescribing Centre 2000). “Managing Medicines across the Health Economy” outlined a fitness for purpose framework for APCs to review and restate their role, or help to identify improvements (National Prescribing Centre 2007b).

In 1989 a review reported that although there had been increased quality in prescribing from the introduction of formularies in UK hospitals and general practice, measurable outcomes were difficult to quantify (Anon 1989). In addition the review described cost reduction as a secondary aim and although clear in general practice this was but less easy to evidence in secondary care where many factors contributed to the drugs bill. Duerden and Walley (1999) reported a lack of examples of successful joint formularies and suggested that with primary care reforms in commissioning the use of joint formularies would reduce problems encountered at the primary and secondary care interface. In addition the authors reported that many local decisions around drug choices would be superseded by national decisions made by NICE. Furness (2000) also reported on the limitations of primary care or joint formulary implementation, citing difficulties such as time constraints, updating and monitoring a formulary list, and concordance at practice level. Smith (2005) reported on the outcome of a national survey conducted by Pharmacy Management Magazine of 220 primary care organisations. The survey reported that 64% of former PCTs were working with a formulary or an approved list of drugs in primary care and that 47% shared a formulary of with their local hospitals. In a survey of all 1099 GPs (43% response rate) in the South West where a joint formulary was in existence, the authors reported an overall positive attitude towards the process particularly towards the educational value and the potential for improving prescribing across the interface (Heal et al 2006).

### **1.7.7 Financial incentives in prescribing and the GP contract**

In the UK, GPs have traditionally been offered a range of financial incentives, via a national contract, that has offered a mix of remuneration including fee for service, capitation, salary and information technology (Smith and York 2004). In addition the traditional GP contract encouraged public health interventions such as vaccinations and screening. Under GP fund-holding, practices that achieved savings from indicative prescribing budgets were able to reinvest this money to improve patient care. In a further initiative the Health Service Circular 1999 / 228 identified to newly formed Primary Care Groups (PCGs), which later became Primary Care Trusts (PCTs), a framework to ensure prescribing incentive schemes were offered to all GP practices. Evaluations of such incentive schemes have provided mixed outcomes. Ashworth et al (2002, 2003) surveyed PCG / PCT prescribing advisors over two consecutive years in London and South East (n = 113, 2000; n = 145, 2001) to investigate the use of prescribing incentive schemes. A reduction of overspending PCGs / PCTs on prescribing budgets in year 2 (38%) from year 1 (88%) and that nearly all had adopted quality prescribing indicators by year 2 within these incentive schemes was reported. However the authors added that many schemes could have been better designed to reinforce the national policy emphasis on quality improvement. In a national survey of all PCGs / PCTs in England, Mason et al (2005) requested original copies of all incentive schemes to explore whether this was a useful approach to encourage quality prescribing. This study identified that many schemes had not been finalised and that although schemes generally covered similar therapeutic areas, they varied considerably in length, complexity and reward structure.

In 2004, following an evaluation of a two year primary care quality improvement scheme pilot project in East Kent, a new contract for general practice was announced (Smith and York 2004) The new contract represented a significant shift in the way GPs worked, and promoted principles of high quality and evidenced based care and consistency in care for patients across the country. A fundamental part of the new contract was the Quality and Outcomes Framework (QOF). The framework created a point based system which remunerated general practices for providing quality care to patients. In order to support QOF, a national IT system, the Quality Management and Analysis System (QMAS), was introduced that provided GP practices and PCTs objective evidence and feedback on QOF performance.

The QOF comprised of a range of criteria referred to as indicators that were linked to both clinical and organisational domains to support the management of long-term conditions such as cardiovascular disease and diabetes (NHS Employers and the BMA 2009). In addition indicators were introduced in relation to systems and process that supported medicines management such as repeat prescribing and medications review.

Roland et al (2005) used both qualitative interviews with 20 GPs and a quantitative survey of 1035 GPs to examine the impact of QOF. Results suggested that although patients were being seen more frequently, particularly in nurse-led clinics, overall there were possible unintended consequences of an incentive driven contract such as reduced continuity of care, care fragmentation, neglect of clinical areas excluded from QOF and damage to internal motivation. Bland (2005) on behalf of the BMA, reported on the success of QOF in improving quality of care and that the prescribing of QOF drugs had not been at the expense of others.

A limited number of studies have evaluated the impact of QOF in relation to prescribing in primary care. Two studies examined attainment within small groups of practices (n = 18, Steele et al 2007, n = 26 Guildford et al 2007) and three have examined national performance data (Tsimtsiou et al 2009, Ashworth et al 2007, Petty and Lloyd 2008). MacBride-Stewart et al (2008) conducted a review including 92 practices within one NHS region in Scotland. A common theme identified was the relationship between rising prescribing levels of QOF drugs compared to non-QOF drugs in relation to QOF scores and or improved clinical management. Steele (2007) reported that the standard of care provided for conditions not presently managed within the QOF had been maintained. Ashworth et al (2007) reported on the relationship of social deprivation to QOF outcomes in coronary heart disease and the use of cholesterol lowering agents. The authors described a 34.5% variation in statin prescribing by GPs and that the most powerful predictors for prescribing were higher social deprivation, higher prevalence of coronary heart disease and achievement of cholesterol targets for diabetics. In addition statin prescribing was reported to be higher in more deprived communities, even after adjustment for increased disease prevalence and practice variables associated with deprivation.

### **1.7.8 The Kings Fund: The quality of GP prescribing**

“Improving the quality of care in general practice” was the most extensive review of quality across general practice (The Kings Fund 2011). One part of the inquiry focussed on GP prescribing with specific reference to the patients’ perspective and to their ‘journey’, and the effect of prescribing on patient safety (Duerden et al 2011). This comprehensive study included a literature review of GP prescribing, and a scoping review for guidance and commentary from professional bodies and organisations. The authors reported that a clear definition of prescribing quality was elusive and that any description was guided by the wide range of stakeholder groups involved in the prescribing process either from an academic, clinical, managerial or commercial perspective. The review highlighted the need to improve knowledge about pharmacology and therapeutics, to enhance prescribing support systems, drug monitoring, prescription reviews, and communication with patients in order to achieve concordance. The authors reported that a clear definition of prescribing quality was elusive and that any description was guided by the wide range of stakeholder groups involved in the prescribing process either from an academic, clinical, managerial or commercial perspective. One of the recommendations was to develop quality indicators in relation to prescribing including the use of computerised decision support systems (CDSS). In the UK a shift from paper based to paperless medical records within GP practices had introduced a range of benefits such as automated restructuring of records, speeding, guiding, and validating data input such as through templates and the availability of CDSS (Purves 1996).

Despite the years the original definition of prescribing quality by Parish (1973) placing it in the context of a cash-limited health service is a stark reality considering the current financial climate within the UK economy including the NHS. Over the decades a number of Government schemes and initiatives have been introduced in order to curtail an escalating drugs budget. In 2010 the Government announced in the White Paper “Equity and excellence: Liberating the NHS” that it would release up to £20 billion of efficiency savings by 2014 which would be reinvested to support improvements in quality and outcomes (Department of Health 2010). With the NHS targeting continued efficiency savings one specific CDSS that offers cost effective prescribing choices to GPs at the point of prescribing including has been increasingly commissioned by the NHS for use by GPs (Anon 2010a).

### **1.8 Computers in UK general practice**

Computers first entered UK general practice in the early 1970s, initially designed to collate epidemiological data by enthusiasts. Much of the pioneering use of computers during GP consultations took place in Exeter, particularly at the Ottery Health Centre which during the late 1970s, operated a computerised system that was fully integrated with the local hospital, allowing general practitioners and hospital staff to share the same information, subject to access controls (Benson 2002). Early experimental systems were often paid for by GPs until the “Micros for GPs” scheme, a Government sponsored program to encouraged national take up of computer systems (Benson 2002a). However progress was relatively slow due to constraints of money and time and to uncertainties about the most appropriate hardware and software to use (Jones 1986). Two computer suppliers in the late 1980s introduced schemes whereby practices were provided free systems in return for comprehensive data on morbidity and prescribing which could be sold to pharmaceutical companies for post marketing surveillance, market research and clinical trials (Benson 2002a). These schemes were soon scrapped when Government eventually introduced a direct reimbursement scheme in 1989. This led to a dramatic increase in uptake and by the 1990s over 50 commercial systems were available with 8,500 practices fully computerised (Millman et al 1995). Technical improvements allowed improved functionality such as links to pathology laboratories, internet access, and data management to support clinical audit. In addition computers transformed prescription management systems, because illegible handwriting has been widely acknowledged as a major cause of medical error (Bruner and Kasdan 2001).

### **1.9 Computerised decision support systems (CDSS)**

Wyatt (1991a) has described a deductive approach to decision making by clinicians from symptoms to aid diagnosis by drawing on medical knowledge to form one or more hypothesis about their cause. Historically medical knowledge to aid decision making has been in a conventional format such as books, journals, discussion with colleagues or through educational meetings (Wyatt 1991a). The negative aspects of books and journals include their size and number, storage, reliability, publication bias and need for updating. Computers introduced a novel concept in that apart from being able to store medical knowledge they also allowed this knowledge to be manipulated as text meaningful to users, but also encoded as symbols meaningful to computers (Wyatt 1991b). Encoding this knowledge allowed better user interaction to locate data from the knowledge base and to act as both a teaching and medical decision aid.

Wyatt (1991b) described computerised medical decision aids as best classified by their clinical role, citing early examples of their use in medicine for interpreting abnormal data e.g. laboratory results or patient specific data to aid clinical diagnosis.

With the expansion of computer use within healthcare settings interest emerged in CDSS, with initial development aimed at aiding diagnosis and dose calculations. However this led to the development of GP and pharmacy systems to support prescribing via alerts to warnings on drug interactions, allergies and contraindications (Barber 2004). Shortliffe (1987 p61) defined CDSS as “any computer program designed to help health professionals make clinical decisions.” The author described three levels or tools for support from a generalised level to a patient specific level, as either:

- Tools for information management: e.g. hospital information systems to access patient data or bibliographic retrieval systems
- Tools for focussing attention: e.g. clinical laboratory systems that flag abnormal values
- Tools for patient specific consultations: e.g. programs that provide customised assessments or advice based on sets of patient specific data

This broad definition included any computerised system such as electronically available books and journals. Wyatt and Spiegelhalter (1992 p3) provided a more specific approach to CDSS defining it as “active knowledge systems which use two or more items of patient data to generate case-specific advice.” From an operational perspective in terms of how CDSS are used within clinical settings; Haijoff (1998) described a simple classification model of a CDSS being either passive or active. In passive systems the user would interrogate the CDSS for information that was not patient specific, such as an electronic formulary or a clinical guideline. In contrast active systems would aid the user at a patient specific level often through the interaction of electronic or computerised databases such as providing simple drug alerts, reminders or more sophisticated systems that supported diagnosis or disease management. A range of techniques have been utilised in the design methodology of CDSS ranging from simple logics such as problem specific algorithms to more complex mathematic modelling, and the predominant Bayesian statistics, decision analysis and the computer science subfield known as “artificial intelligence” (Shortliffe 1987).



Thornett (2001) described these techniques from an operational perspective as one of two levels of CDSS. A simplistic level that encouraged users to follow a logical approach to decision making or a “rule based system” or in contrast to more complex “expert system”, that could answer medical queries and provide patient tailored advice.

### **1.9.1 Rule based systems**

These encourage the user to think through decisions logically and to enter data logically similar in fashion to large flow charts. Commonly available as electronic protocols these systems present information in context and in response to prompts or steps that guide for example drug choice or a possible diagnostic strategy (Delaney et al 1999). One example of such a system in the UK is the NHS Direct triage service that provides advice to health professionals during telephone consultations. These systems rely on the application of a set of rules which that are based on clinical or demographic characteristics or the results of previous steps. In addition the rationale behind the rule set may range from national guidance, expert opinion or examples of best practice. In addition due to their nature these systems reflect a gradual accumulation of data and assimilation into practice. Another common example of a rule based system are reminders and alerts that are linked to screening, immunisations or drug therapy such as warnings and drug interactions.

### **1.9.2 Expert based systems**

Expert-based systems operate through a series of interactions between a database of knowledge e.g. clinical guidelines, a decision making component and the patient record that present to the end-user clinician as an interface framework within the healthcare setting (Haijoff 1998). These systems attempt to model the thought process of the human mind by selecting additional rules based upon a set of hypotheses (Thornett 2001). Often known as probabilistic systems, patient data is modelled to predict possible future health interventions or outcomes. An advantage of this model is that knowledge is separated from inference and in addition systems can be readily updated exemplified in the UK with the availability of cardiovascular risk calculators (Delaney et al 1999).

### **1.10 Discussion**

Protti (2005) suggested that although modern society had adapted to computerised technology with innovations seen in a range of industries, healthcare had continued to lag behind with the overwhelming majority of computers used for simple accounting and statistical reporting. The author added that due to the lack of adequate support systems, most clinicians continued to practice 'memory-based medicine.' Delaney et al (1999) reported that despite the UK having the most extensively computerised primary healthcare system it was surprising that CDSS was not commonplace, citing a number of factors such as the absence of national agreed standards. The authors concluded that although CDSS had demonstrated benefits such as in the management of anticoagulation further research was required in patient orientated outcomes and that that despite the huge potential in its use the concept had largely failed due to the failure to examine the needs of practitioners more closely. Coiera et al (2006) reviewed the literature in relation to the safety and quality of CDSS in both primary and secondary care from the UK and abroad. The author described CDSS as a potent intervention that improved the quality, safety and effectiveness of clinical decisions however uptake levels had remained low. It has been estimated that thousands of CDSS have been made available for use by clinicians within healthcare settings (Morris 2002). In addition despite the huge investment of time and money into these CDSS little is known of the tens or hundreds that have been embarked on but have failed (Barber 2004).

## **Chapter 2**

# **Computerised Decision Support Systems (CDSS): A scoping review**

## **2.1 Introduction**

The previous chapter outlined how CDSS was identified as a specific area for further investigation for improving the quality of prescribing by GPs. In order to identify international literature on the use of CDSS within primary care settings a number of additional methodologies were considered including the use of scoping reviews. When evaluating evidence, Stephens (2005) described systematic reviews of well-designed randomised controlled trials as the gold standard. Systematic reviews use a transparent process to define a research question, search for published studies and to assess their quality (Armstrong et al 2011). A crucial step in the systematic review process is to define the scope of the research question, and this requires an understanding of existing literature, including gaps, uncertainties and clarification of definitions related to the research question. However an increasingly popular way to collate important background information and assess the existing evidence base of a subject area is to conduct a scoping review (Armstrong et al 2011).

## **2.2 Scoping reviews**

A key difference between scoping reviews and systematic reviews is that the scoping review provides an overview of existing literature usually without assessing the quality of included studies (Armstrong et al 2011). Scoping reviews are commonly described as following a mapping process that summarises a range of evidence in order to convey the breadth and depth of a particular field (Levac et al 2010). A scoping study can determine the size and nature of the evidence base for a particular topic area, which in turn can be used to identify gaps in the literature and make recommendations for future research. Anderson et al (2008) described scoping reviews as imprecisely defined, but were commonly non-systematic reviews of a subject area. A summary of the key differences between systematic reviews and scoping reviews is shown in Table 2.1

**Table 2.1 Key differences between systematic reviews and scoping reviews**  
**(adapted from Brien et al 2010)**

<b>Systematic Reviews</b>	<b>Scoping Reviews</b>
Focused research question with narrow parameters	Research question(s) often broad
Inclusion / exclusion criteria usually defined at outset	Inclusion / exclusion criteria can be developed post hoc
Quality filters often applied	Quality not an initial priority
Detailed data extraction	May or may not involve data extraction
Quantitative synthesis often performed	Synthesis more qualitative, and typically not quantitative
Formally assesses the quality of studies and generates a conclusion relating to the focused research question	Used to identify parameters and gaps in a body of literature

A number of different approaches to scoping reviews have been reported. Arskey and O'Malley (2005) described a step-wise approach as part of a methodological framework to scoping. Anderson et al (2008) described a process of mapping the relevant literature, policy, stakeholder consultation and conceptualisations of the research area, however the authors stated that this was by no way comprehensive or restrictive. In the UK the Service Delivery and Organisation Research Program (SDO) has had extensive experience of commissioning and using scoping reviews within the health service (Anderson et al 2008). Key lessons from the SDO included the need for scoping teams to be multi-disciplinary, have sufficient time to integrate diverse findings and the need for research commissioners to be explicit about the aims and intended use of scoping studies. In the UK examples of scoping reviews used to evaluate aspects of prescribing within primary care have included the extent and uptake of nurse and pharmacist supplementary prescribing (Bissell et al 2008). , and the quality of prescribing by GPs (Duerden et al 2011).

In both of these studies the research teams complemented healthcare database searches with a range of additional methods in order to obtain further evidence and literature in relation to the specific subject areas including engagement with stakeholders. Bissell et al (2008) reported a scoping review strategy that included a thematic review of published and grey literature, interviews with key stakeholders involved in supplementary prescribing, a postal questionnaire survey of nurses (n=518) and pharmacists (n=411). In addition ten detailed case studies of supplementary prescribing practice were included supported by observations, interviews and prescribing data. In a scoping review of the quality of GP prescribing in the UK, Duerden et al (2011) obtained guidance and commentary from professional bodies and organisations using an initial stakeholder meeting. A further stakeholder event involved 27 attendees from across a range of disciplines and backgrounds to include GPs, academics, NHS Connecting for Health, the CDSS industry and patient representative groups.

Arskey and O'Malley (2005) described a five stage framework underpinned by attributes characterised by systematic reviews as each stage is conducted in a rigorous and transparent way so that the process be documented in sufficient detail to allow the study be replicated by others. A summary of this methodological framework including a description of each stage is shown in Table 2.2.

**Table 2.2: An overview of a methodological framework for conducting a scoping review (adapted from Arskey and O'Malley 2005)**

Framework Stage	Description
1. Identifying the research question	Identifying the research question is the starting point that guides the way which search strategies are developed and conducted. A wide approach is suggested in order to provide breadth of coverage.
2. Identifying relevant studies	This stage involves identifying relevant studies and developing a decision plan at the outset about coverage of the review in terms of time span and language. for where to search, which terms to use, which sources are to be searched, time span, and language. Sources include electronic databases, reference lists, hand searching of key journals, networks, organisations and conferences. Breadth is important however practicalities of the search are as well such as time constraints, budgets and personnel resources as these may be potential limiting factors on the search strategy.
3. Study selection	Study selection involves post hoc inclusion and exclusion criteria based on the specific research question but also an increasing familiarity of the literature was identified and reviewed.
4. Charting the data	A data-charting form is developed and used to extract data from each study which can be a mixture of general information e.g. study population, intervention type and outcomes. A 'narrative review' or 'descriptive analytical' method is used to extract contextual or process oriented information from each study.
5. Collating, summarising and reporting the results	A basic numerical analysis can present the extent, nature and distribution of studies identified.in either tables or charts. An analytical framework or thematic construction is used to provide an overview of the breadth of the literature.

## **2.3 Methods**

For this study a scoping review was selected as the method of choice and was performed based on the methodological framework outlined by Arksey and O'Malley (2005). In the development of a research question, aspects of the research area were considered. The research team had developed a working knowledge and experience of IT within UK general practice and primary care. In addition in the UK, CDSS was widely available within GP clinical systems and community pharmacy computer systems. Drawing on this experience and an overview of the literature, the primary research question was to identify the use and evaluation of CDSS in primary care. The rationale behind this research question was to gain an understanding of the evidence base of CDSS in primary care and to identify opportunities to use this to improve prescribing by GPs in the UK.

### **2.3.1 Identifying relevant studies**

A number of steps were taken firstly to obtain relevant information in the form of published articles and studies available from healthcare databases and then extending the scoping review to include a review of the grey literature. Grey literature was identified using further internet searches, website reviews and personal communication with representatives from the CDSS industry. Table 2.3 summarises the sources of evidence and methods used to obtain the evidence and their outcomes.



**Table 2.3 Methods used to obtain relevant studies and additional evidence**

<b>Evidence Source</b>	<b>Methods</b>	<b>Inclusion / Exclusion Criteria</b>
1. Healthcare database searches from 1990 to 2010 AMED, BNI, HMIC, MEDLINE, EMBASE, PsycINFO, CINAHL, and HEALTH BUSINESS. This search was repeated in March 2011.	Key words, “computerised decision support”, “physician order entry and prescribing”	Inclusion criteria limited to the use of CDSS in primary care settings only. These included in supporting prescribing, clinical guidelines, therapeutic control, medicines management. Other articles of interest were identified including literature reviews of CDSS including expert opinion
2. NHS Connecting for Health (CFH).	Searches and interrogation of the CFH website.	Webpages and policy documents identified
3. National Institute for Clinical Excellence (NICE)	Searches and interrogation of the NICE website.	Web pages and evidence identified
4. Other Sources	Known websites in relation to CDSS and health informatics. Websites visited: First Databank, Script-Switch®, INRstar®. In addition the websites of GP clinical system providers in the UK: EMIS, INPS (Vision), Micro-Test, iSOFT and SystemOne were reviewed.	Web pages and evidence identified
5. Personal Communication	Discussions with representatives from a commercial CDSS supplier. One informal interview and one informal telephone conference call.	Background information on CDSS collated.

### 2.3.1.1 Healthcare database searches

Published studies and articles were identified from healthcare database searches conducted in December 2010 with a date range from 1990 to 2010 using AMED, BNI, HMIC, MEDLINE, EMBASE, PsycINFO, CINAHL, and HEALTH BUSINESS. The results of these database searches are shown in Table 2.4

**Table 2.4 Results of healthcare database searches**

Healthcare databases searched including search terms used	Numbers of citations
AMED, BNI, EMBASE, HMIC, MEDLINE, PsycINFO, CINAHL, HEALTH BUSINESS ELITE; Duplicate filtered: "computerised decision support" AND "prescribing").ti,ab;	114
AMED, BNI, EMBASE, HMIC, MEDLINE, PsycINFO, CINAHL, HEALTH BUSINESS ELITE; Duplicate filtered: ("physician order entry" AND "prescribing").ti,ab;.	219

Three hundred and thirty three references to articles and studies were initially identified from the healthcare database searches. Lists of these citations were printed and reviewed for duplications and against an initial set of inclusion and exclusion criteria, to include studies of CDSS within primary care settings only as follows:

#### Inclusion criteria

- Reports, studies and articles in relation to CDSS within primary care settings
- Limited to use by GPs, however in UK studies were included that referred to use by nurses in either general practice or other primary care settings
- Limited to the UK, USA, Australia and Europe
- Relevant background literature in relation to health informatics and CDSS

#### Exclusion criteria

- Reports, studies and articles in relation to CDSS within secondary or tertiary care settings
- Reports, studies and articles in relation to CDSS within pharmacies
- Literature in relation to related to wider aspects of healthcare delivery namely electronic health records, electronic transfer of prescriptions and systems or frameworks supporting this process.

References of selected studies were checked for any additional sources of information. The healthcare database searches were repeated in March 2011 and 3 additional articles were identified.

### 2.3.1.2 Website reviews

Further evidence was obtained from a number of website searches to include NHS Connecting for Health (CFH), the National Institute of Clinical Excellence (NICE) and commercial providers of CDSS are summarised in Table 2.5

**Table 2.5 Summary of website searches of commercial providers of CDSS**

Website	Summary
NHS Connecting for Health (CFH):	<ul style="list-style-type: none"> <li>• Accessed March 2011</li> <li>• Documentation from either web pages or policy documents in relation to CDSS availability</li> </ul>
The National Institute of Clinical Excellence (NICE)	<ul style="list-style-type: none"> <li>• Accessed in December 2010 and March 2011</li> <li>• Documentation from either web pages or published evidence to support the use of CDSS from technology appraisals or for the use in supporting the implementation of clinical guidelines.</li> </ul>
Commercial providers of CDSS	<ul style="list-style-type: none"> <li>• Accessed March 2011</li> <li>• First Databank<sup>®</sup></li> <li>• Script - Switch<sup>®</sup></li> <li>• INR-Star<sup>®</sup></li> </ul> <p>In addition the websites of the five GP clinical system suppliers EMIS, INPS (Vision), Micro-Test, iSOFT and SystmOne were reviewed.</p>

### 2.3.1.3 Personal communication

In May 2011 personal communication with a CDSS representative was made by the lead researcher (NC) and an informal meeting was arranged. This meeting was held in June 2011 where background information was collated on the CDSS industry in the UK, and further information with regard to the availability of additional published evidence. In addition a telephone conference call was arranged by the researcher (NC) and other representatives from the same CDSS supplier which was conducted in July 2011.

### **2.3.2 Study selection**

Studies and articles were all checked against the inclusion and exclusion criteria.

### **2.3.3 Charting the data**

This stage of the scoping review involved charting aspects of evidence identified and to support this a data charting form was created using Microsoft Excel to include the following information where possible:

- Author (s)
- Year of publication
- Source i.e. publication title or website name
- Country of origin
- Type of intervention and or design
- Aims of study if applicable
- Relevant results
- Relevant outcome measures

The evidence identified was then characterised in one of four types of evaluation of the research area; systematic reviews of controlled trials of the use of CDSS, reports or evaluations of CDDS either in development or in use, evaluations of CDSS from the perspective of end users (qualitative or quantitative) and general literature from publications to include journal articles, expert opinion and from book chapters.

## **2.4 Results**

A total of 333 citations were identified from searching the literature databases, from which after screening and further checking 150 were determined as relevant to this scoping review. Figure 2.1 shows a flow diagram of the steps followed during the scoping review and the results obtained. Characterisation of data identified from the scoping review of CDSS is provided in Table 2.6.

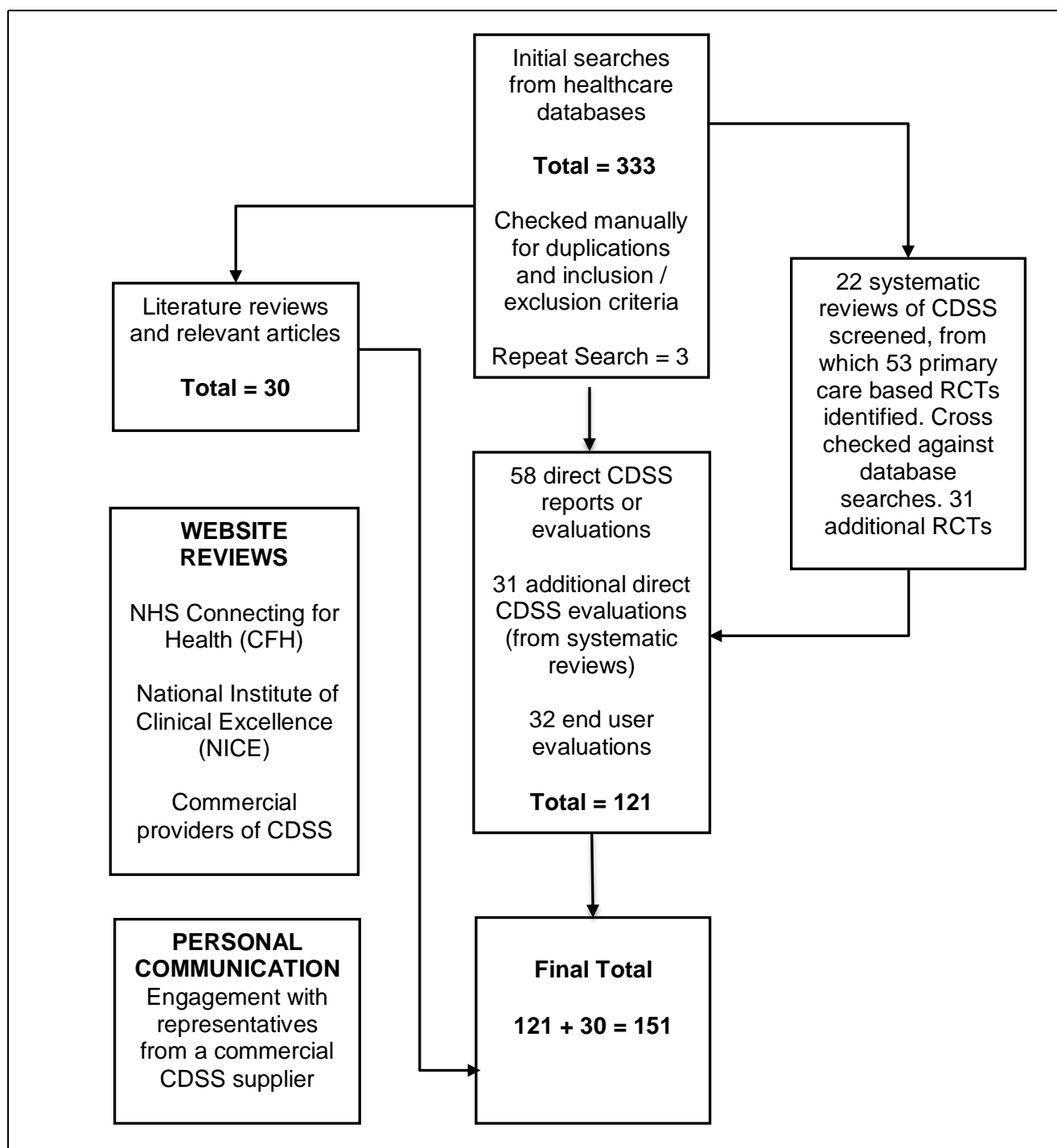


Figure 2.1: Flow diagram of the steps followed during the scoping review

**Table 2.6 Characterisation of data identified from the scoping review of CDSS**

<b>Evidence Form</b>	<b>Data Source</b>	<b>Summary of outcomes</b>
Systematic Reviews	22 systematic reviews of controlled trials including RCTs. Reviews were of a range of parameters including prescribing, drug dosing, drug monitoring and clinician performance.	From these reviews 53 RCTs were identified of CDSS in use from the USA, UK and Europe based in primary care settings that were published from 1990. All of the RCTs were checked against the healthcare database searches for duplication, 31 additional RCTs identified.
Evaluations or reports of CDSS in use	Studies or reports of CDSS in use or in development including prototypes from the UK, Europe and abroad including the USA in primary care settings.	58 articles identified on the use of CDSS in primary care either from descriptive reports, testing, trials of CDSS (including RCTs) and retrospective analysis of use
End user evaluations of CDSS	Primary care based studies that evaluated CDSS from an end user perspective.	31 studies identified of which 19 were from the UK. Methods used included interviews, focus groups, observational studies and surveys.
Other supporting literature	Articles including relevant literature reviews, articles, conference abstracts editorials, a university tutorial, and book chapters.	A range of supporting literature on CDSS including historical aspects to decision making, defining CDSS and use in healthcare settings. Websites identified were interrogated and data collated from either web pages or available documents

### **2.4.1 Systematic reviews**

Twenty two systematic reviews of a range of controlled trials, including randomised controlled trials (RCTs) in relation to CDSS were identified from the scoping review and these examined a broad range of parameters including prescribing, drug dosing, drug monitoring and clinician performance. Three reviews were updates from previous studies (Hunt et al 1998, Garg et al 2005, Durieux et al 2008) whereby additional trials were added. Evaluations of CDSS demonstrated positive outcomes in terms of improvements in prescribing (Yourman et al 2008), clinician performance (Garg et al 2005), adherence to guidelines (Jamal et al 2009) and drug dosing and therapeutic response (Durieux et al 2008). In contrast other systematic reviews highlighted a lack of high quality studies that demonstrate improved patient outcomes (Mollon et al 2009), a need for better implementation strategies (Bryan and Boren et al 2008) and an increase in the risk of adverse events or mortality (Eslami et al 2007a).

Summarised in Table 2.7 are 15 of the 22 systematic reviews that included primary care based trials. Of these only two (Bryan and Boren 2008, Eslami et al 2007a) specifically focussed only on the use of CDSS within in primary care settings. The other 13 reviews included data from studies from both primary and secondary care settings. Four of the systematic reviews included trials based in secondary care settings only (Walton et al 1999, Walton et al 2001, Kaushal et al 2003, Eslami et al 2007b, Main et al 2010). Of the 11 RCTs identified by Kawamoto et al (2005), 2 of the primary care based trials were from the 1980s. All of the 7 trials identified by Fitzmaurice et al (1998a) in relation to anticoagulation were either pre-1990 and or based in secondary care. Bryan and Boren (2008) identified 17 studies including 5 non-randomised observational studies and 12 RCTs; all based in primary care settings. Of the 12 RCTs, 2 were from the UK, 1 from Italy and 9 from the USA. Thirteen studies (76%) found either positive or variable outcomes related to CDSS intervention with 4 studies (24%) showed no significant effect. Although CDSS was found to have the potential to produce statistically significant improvement in outcomes, there was much variability among the types and methods of CDSS implementation and resulting effectiveness. The authors recommended that further work was needed to determine effective implementation strategies for the use of CDSS across multiple settings and patient populations.

Eslami et al (2007a) evaluated the impact of CPOE on patients in primary care settings from 30 studies. Of these 3 were based in the UK. Outcome measures included the adherence to alerts, safety, time, organisational efficiency, satisfaction, usage and usability. Although CPOE appeared to support the adherence to guidelines, the authors concluded that overall there was little evidence available that demonstrated CDSS improved safety measured by medical errors or adverse events. After checking for duplication amongst the systematic reviews 53 RCTs specifically undertaken in primary care from 1990 were identified. A number of studies were identified but not selected as they were either non-randomised trials or observational studies. Once checked for duplication against the healthcare database searches 31 of the RCTs identified were then included as part of the final scoping review.



**Table 2.7 Systematic reviews of CDSS**

<b>Authors</b>	<b>Aims</b>	<b>Methods</b>	<b>Results</b>	<b>Outcomes</b>
Austin et al (1994)	To assess the clinical value of electronic reminders	Meta-analysis was used to combine quantitative data from 10 RCTs selected from the Columbia registry. Trials were conducted in family or internal medicine clinics all based in the USA.	Four trials concerning immunisations or cervical screening were included in the final analysis. Evidence for the use of reminders in tetanus immunisation was much stronger than that for cervical screening.	Electronic reminders were an effective information intervention that could improve compliance for these two preventative healthcare procedures.
Bennett and Glasziou (2003)	To systematically review controlled trials of electronic medication reminders or feedback directed to healthcare providers or patients	Healthcare database searches, reference list reviews and searches of conference proceedings. A total of 76 studies were identified of which 26 were selected that made 29 comparisons of medication management to a control group.	RCTs were included from both primary and secondary care settings, 24 from the USA, 1 from Norway and 4 from the UK. Examples of reminders from primary care trials included disease management and clinical guidelines, investigations, specific drug related messages and drug switching recommendations.	Heterogeneity of trials prevented meta-analysis. Reminders were found to be more effective than feedback in modifying clinician behaviour.
Bryan and Boren (2008)	To evaluate the use and effectiveness of CDSS from controlled trials within primary care settings.	Healthcare database searches. Studies were selected for review if they involved CDSS as a single intervention and included quantifiable outcome measures.	Seventeen studies were included in the review, including 12 RCTs, of which 2 were from the UK, 1 from Italy and 9 from the USA. Thirteen studies found either positive or variable outcomes related to CDSS intervention with 4 studies showed no significant effect. All were primary care based studies.	CDSS was found to be a validated intervention that had the potential to produce statistically significant improvement in outcomes. Variability was found amongst the types and methods in the implementation of CDSS

**Table 2.7 Systematic reviews of CDSS (cont.)**

Authors	Aims	Methods	Results	Outcomes
Durieux et al (2008)	To assess from controlled trials whether CDSS advice on drug dosage had beneficial effects on the process or outcome of healthcare. An update of a previous study (Walton et al 2001)	Healthcare database searches. Hand searches of relevant and reference lists from primary articles	26 comparisons (23 articles) met the inclusion criteria. 7 trials were based in primary care settings 3 from the UK, 1 from France, 1 from Canada and 1 multicentre study across Europe. 16 trials were based in secondary care settings, 11 from the USA and 5 from across the world.	CDSS to support drug dosing had some benefits that led to a more rapid therapeutic control. It also reduced the risk of toxic drug levels and the length of time spent in hospital, however it had no effect on adverse events.
Eslami et al (2007)	To evaluate the impact of CPOE on patients in primary care settings.	Healthcare database searches. Studies that included CDSS that were not part of CPOE systems were excluded.	30 studies were included for final analysis. Outcome measures were adherence to alerts, safety, time, organisational efficiency, satisfaction, usage and usability. Of the 30 studies 3 were from the UK. All studies were based in primary care	Although CPOE appeared to support the adherence to guidelines, overall little evidence was available in improving safety measured by medical errors or adverse events.
Garg et al (2005)	To review controlled trials assessing the effects of CDSS and to identify study characteristics predicting benefit. This study was an update from Hunt et al (1998).	Healthcare database searches. Studies were included that evaluated the effect of CDSS on practitioner performance or patient outcomes.	100 studies were included for final analysis with 55 from primary care. CDSS improved practitioner performance in 62 (64%) of the 97 studies assessing this outcome including the use of diagnostic systems, reminder systems, disease management systems, and drug-dosing or prescribing systems.	Improved practitioner performance was associated with CDSS that automatically prompted users compared with those requiring users to activate the system. However the effect of CDSS on patient outcomes was understudied and when studied was found to be inconsistent

**Table 2.7 Systematic reviews of CDSS (cont.)**

<b>Authors</b>	<b>Aims</b>	<b>Methods</b>	<b>Results</b>	<b>Outcomes</b>
Hunt et al (1998)	To assess the effects of CDSS on clinician performance and patient outcomes. An update from a previous study (Johnstone et al 1994)	Healthcare database searches. Reference lists and conference proceedings reviewed. An update of an earlier study, adding searches from 1992–1998.	68 controlled trials were characterised to evaluate a range of uses of CDSS such as drug dosing, diagnosis, and disease management.	Published studies of CDSS were increasingly of an improved quality. CDSS was found to enhance clinical performance in drug dosing, preventative care and other aspects of medical care. The effect on patient outcomes was found to be insufficiently studied.
Jamal et al (2009)	To assess the impact of information technology on the quality of healthcare	Healthcare database searches. Searches for relevant conference proceedings a review of reference lists.	A total of 23 studies were included for final analysis including 8 RCTs of which 7 were from primary care. A positive improvement, in relation to their compliance with evidence-based guidelines, was seen in 14 studies.	As with similar previous reviews information technology increased clinicians' adherence to guidelines.
Johnston et al (1994)	To review the evidence from controlled trials of the effect of CDSS on clinician performance and patient outcomes.	Healthcare database searches. Conference proceedings and reference lists reviewed.	28 controlled trials were included for final analysis. Studies were of the use of CDSS in supporting drug dosing, diagnosis, preventative care reminders and clinician performance.	Strong evidence was identified that some CDSS could improve physician performance. Further well designed studies were needed to evaluate their effects and cost effectiveness particularly on patient outcomes.

**Table 2.7 Systematic reviews of CDSS (cont.)**

<b>Authors</b>	<b>Aims</b>	<b>Methods</b>	<b>Results</b>	<b>Outcomes</b>
Mollon et al (2009)	A systematic literature review of CDSS for features predicting the success of CDSS for Prescribing	Healthcare database searches. Studies were screened for 28 pre-determined system features	41 RCTs met the inclusion criteria of which were from both primary and secondary care settings. 23 trials were conducted in primary care settings with 4 from the UK, 12 from USA and 5 from Europe	Statistical analysis was not able to be done due to the small number of studies and lack of diversity of outcomes. While CDSSs have potential to change health care provider very few high quality studies to show patient outcome improvements.
Moxey et al (2010)	A systematic review to explore the barriers to, and facilitators of CDSS	Healthcare database searches	Most studies explored clinician's opinions of a specific CDSS (n = 50). 38 were in primary care of which 35 from the USA.	Despite advances in technology and CDSS sophistication, most factors were consistently reported over time and across ambulatory and institutional settings.
Pearson et al (2009)	A systematic review to evaluate if CDSS changed prescribing practice	Healthcare database searches.	56 studies met the inclusion criteria of which 38 addressed initiating, 23 monitoring and three stopping therapy. 46 RCTs were from primary care settings of which 6 were from the UK.	CDSS that impacted on specific aspects of the prescribing process remained relatively limited. Future implementation was suggested to be built on effective approaches including the use of system-initiated advice to address safety issues and improve the monitoring of therapy.

**Table 2.7 Systematic reviews of CDSS (cont.)**

<b>Authors</b>	<b>Aims</b>	<b>Methods</b>	<b>Results</b>	<b>Outcomes</b>
Schedlbauer et al (2009)	A systematic review to gather evidence of the types of alerting and reminding mechanisms that were in use.	Healthcare database searches. Trials included if they were RCTs, time series analysis and before and after studies.	Twenty studies were included for final inclusion however due to considerable variation in characteristics of these trials pooling of data was not appropriate. Studies were characterised as describing either basic or advanced alerts. Only 4 of the studies were RCTs, 2 based in primary care.	Most of the studies that evaluated the effects of prompts and alerts on prescribing behaviour showed positive, outcomes. This review was used as part of report for NHS Connecting for Health although none of the studies included were from the UK
Sintchenko et al (2007)	A systematic review of the evidence associating the use of CDSS and improved patient outcomes	Healthcare database searches. Reference lists of articles checked	Twenty four RCTs were selected for final analysis of which 14 were from primary care settings. 6 of the RCTs were from the UK.	Published RCTs of CDSS were found to be more effective in secondary care settings. CDSS was found to improve prescribing practice in acute illness but was less effective in changing clinician performance or health outcomes in primary care
Yourman et al (2008)	Systematic review of CDSS to improve prescribing in the elderly	Healthcare database searches. Studies were eligible if they described a CDSS intervention intended to improve medication prescribing in adults aged over 60 years.	Of those 10 studies testing CDSS interventions, 8 showed at least modest improvements in prescribing, Findings for the impact of CDSS interventions on clinical outcomes were mixed and were reported for only 2 studies. Of the 7 primary care studies 1 from UK, 2 from Canada and 4 from USA	Various CDSS was found effective in improving prescribing but few studies reported improvements in clinical outcomes.

### **2.4.2 CDSS and international experience in primary care**

From the results a wide range of clinical and therapeutic areas were identified where CDSS had either been investigated or used in both developmental and or actual use. Evidence of the use of CDSS from the 121 evaluations either from direct use or from experiences from end users within primary care settings included 49 (41%) from the USA, 47 (38%) from the UK, 8 (7%) were from Australia and 4 (3%) were from Canada. The remaining 11% of studies were from the following European countries: Denmark (1), France (1), Holland (4), Ireland (2), Italy (1), Norway (3) and Spain (1).

In the USA electronic prescribing systems supported by CDSS are often described in relation to computerised physician order entry (CPOE), which integrates other electronic systems such as pathology, radiological investigations and medication orders (Groundrey-Smith 2008). However despite this experience and reported benefits which include a reduction in prescribing and medication related errors, these benefits may not be realisable in the UK due to differences in health service structure, clinical practice, medicine costing and reimbursement systems (Groundrey-Smith 2006).

With CPOE systems predominantly based within hospitals, primary care experience of CDSS in the USA has remained limited. However notable experience has been reported from a number of sites that introduced local prescribing systems and where controlled trials that have evaluated CDSS have shown positive outcomes in supporting prescribing in paediatrics (Christakis et al 2001, Davis et al 2007), antibacterial prescribing (Samore et al 2005) and disease management (Rossi and Every 1997, Sequist et al 2005, Lester et al 2005, Roumie et al 2006, Hicks et al 2008). In contrast a number of other trials demonstrated poor outcomes such as adherence to guidelines (Tierney et al 2003) and low response rates to alerts (Judge et al 2006). Montori et al (2002) reported that a planned care model supported by CDSS in management of diabetes was associated with improved performance but not on metabolic outcomes. A lack of improvement or benefits in terms of patient outcomes was also described with CDSS supporting the management of cardiovascular disease (Tierney et al 2003) and chronic obstructive airways disease (COPD) patients (Tierney et al (2005). From a retrospective analysis of 3481 consecutive drug alerts in primary care practices that used a common CPOE system for prescription writing, Weingart et al (2003) reported that GPs overrode 91% of drug allergy and 89% of high-severity drug interaction alerts.

In a larger retrospective analysis of 233,537 medication safety alerts generated by 2,872 clinicians, Isaac et al (2009) reported an override rate of 77% of allergy alerts and between 57% to 98% of high severity drug interaction alerts with the authors concluding that medication alerts were possibly inadequate in protecting patient safety.

A number of studies including end user evaluations of CDDS within primary care in the USA have reported on a mixture of views and experiences. These have included the nature and intrusiveness of alerting systems (Krall and Sittig 2001) and their specific usability and usefulness (Krall and Sittig 2002). In a survey of 725 GPs and 142 pharmacists the respondents reported mixed views regarding the effect of CPOE on their roles and that alerts provided were useful but still required additional work and improvements to increase their clinical utility (Ko et al 2007). Sittig et al (2006) reported from a survey of 225 GPs that although the majority of CDSS alerts were not explicitly followed and the participants felt they were useful and would be more beneficial if they had more time available to address them.

Other notable reports CDSS experience within primary care from either controlled trials or end user evaluations from other countries included Canada (Lowensteyn et al 1998, Tamblyn et al 2003, Field et al 2009), Australia (Ahearn et al 2003, Bennett et al 2003, Swiedan et al 2009, Swiedan et al 2010, Robertson et al 2011) and some European countries (Poels et al 2008, Fillipi et al 2003, Martens et al 2007).

End user evaluations from Australia reported a similar mixed picture in terms of views and experiences of CDSS. In a national survey of over 3000 GPs McInnes et al (2006) described positive outcomes in terms the introduction of CDSS and electronic prescribing systems in reducing medication errors. In contrast a number of evaluation have reported on drawbacks such as ignoring alerts and missing important drug interactions (Ahearn et al 2003), a lack of agreed national standards (Ahearn et al 2003, Robertson et al 2011), the need for better integration of CDSS with GP clinical systems (Robertson et al 2011) and for CDSS developers to recognise GP practice concerns over costs and time constraints Robertson et al 2011). Using a modified Delphi process with a 12-member multidisciplinary expert panel, Sweidan et al (2010) identified 114 features of e-prescribing software systems including CDSS that would support safety and quality and could be used to develop software standards, and adapted if necessary for use in other settings and countries.

### **2.4.3 CDSS and UK experience in primary care**

The scoping review identified 46 relevant articles and studies including randomised controlled trials that had reported on either the development, use of, or evaluation of CDSS in the UK and these are summarised in Table 2.8. Experience of CDSS was identified in areas such as chronic disease management, implementation of clinical guidelines, triaging, and prescribing support to include the use of drug related warnings, alerts and dosage or therapeutic control. Evaluations were of both prototype CDSS and of those in use such including 14 RCTs. In addition 11 studies involved GPs and nurses as end users of primary care CDSS reported on the use of and perceptions towards CDSS either from surveys or qualitative studies such as interviews and focus groups.

Although the majority of evidence in relation to the use of CDSS is from GPs experiences, there were studies which described CDSS from a nursing perspective (Robinson 2004) and in the provision of nurse led primary care services such as in anticoagulation management (De Lusignan et al 2004). In an evaluation of four types of CDSS used in triaging by NHS Direct, O’Cathian et al (2003) reported on large differences in outcomes when nurses were presented with 119 case scenarios developed from actual calls made to ambulance services. In a national survey of nurses employed in both NHS hospitals and in primary care settings Mitchell et al (2009) identified 141 different CDSS in use of which 33 were used within primary care settings in either maintaining electronic patient records, triage, assessment, or prescribing.



**Table 2.8 UK experience of CDSS within primary care settings**

Author	Type of Evidence	Main outcomes
Anon (2010a)	Review article describing Script-Switch (Drugs and Therapeutic Bulletin)	The authors have reported that this CDSS has been increasingly being commissioned by PCTs and that the NHS has been targeting efficiency savings this CDSS could be very important in offering cost effective drug choices
Avery et al (2005)	Two - round electronic Delphi survey, completed by a 21-member multidisciplinary expert panel, all from the UK	There was a high level of agreement among the expert panel members that indicated clear themes around the need for the improvement of safety features in GP clinical computing systems
Avery et al (2007)	Qualitative study using semi-structured interviews with 31 participants, representing relevant disciplines and interest groups	There were significant opportunities for the improvement in the safety features of general practice computer systems
Broderwick (1999)	Review article published by National Prescribing Centre (NPC) on PRODIGY, a CDSS for use in GP practices	Background to the PRODIGY project, how it was used and rolled out to GP practices in the UK
Chapman (2007)	Development of CDSS to aid prescribers in the management of stroke and diabetes	Report describing the work of Keele University.
De Lusignan et al (2004)	To evaluate the implementation of a primary care, nurse-led, near patient anticoagulant monitoring service. Action research workshops, supported by questionnaires and clinical audit involving staff from 13 GP practice	The group shared their experiences and developed an understanding of when it might be appropriate to vary from the CDSS recommendations and how this could be audited
Eccles et al (2000)	A before and after cluster RCT (The COGENT Study). See Eccles et al (2002)	Initial report of a proposed study of a CDSS
Eccles et al (2002)	A cluster RCT to study the effect of a CDSS on managing computerised evidence based guidelines on managing asthma and angina involving 60 GP practices in the North East of England	The CDSS (PRODIGY) was found to have no significant effect on consultation rates, process of care measures (including prescribing), or any patient reported outcomes for either condition. Levels of use were low
Edgeworth and Coles (2010)	A retrospective paired before and after study that compared anticoagulant management in secondary care for the year prior to the introduction of near-patient testing in a single GP practice, and in the subsequent year after it was introduced.	The primary care results were slightly poorer than secondary care based, although the authors maintained these were not clinically or statistically important.

**Table 2.8 UK experience of CDSS within primary care settings (cont.)**

<b>Author</b>	<b>Type of Evidence</b>	<b>Main outcomes</b>
Emery et al (2000)	Cross-over experiment with balanced block design to assess a CDSS with 41 GPs to interpret family history of breast and ovarian cancer	The use of this CDSS could enable GPs to be more effective gatekeepers to genetics services
Fernando et al (2004)	Laboratory testing of 4 of the main GP clinical systems against a list of 18 theoretically derived scenarios related to safety	The safety features of the 4 systems that covered three quarters of UK general practices were found to have clinically important deficiencies
Fitzmaurice et al (1996)	Evaluation of a CDSS to support oral anticoagulation management by measuring proportions of patients adequately controlled defined as being within INR range	CDSS enabled safe and effective transfer of anticoagulation management from hospital to primary care
Fitzmaurice et al (1998b)	Prospective evaluation of therapeutic control of all patients taking warfarin at one GP practice in Birmingham	CDSS enabled safe and effective transfer of anticoagulation management from hospital to primary care
Fitzmaurice et al (2000)	RCT in 12 primary care practices in Birmingham to evaluate oral anticoagulant management supported by CDSS in primary care compared to secondary care	Care using this method in primary care that supported by CDSS was at least as good as routine hospital follow up
Fitzmaurice et al (2001)	Retrospective follow up to include patients involved a previous study (Fitzmaurice et al (2000))	Within these practices, oral anticoagulation management was safe and effective
Fitzmaurice et al (2002)	RCT of 49 patients from 6 GP practices randomised to either self-management or routine primary care anticoagulation management	First UK data to show self-management was as safe as primary care management.
Fitzmaurice et al (2005)	Multi-centre open RCT in the Midlands involving 2530 patients from 49 from GP practices identified to determine effectiveness of self-management compared to routine care	No significant differences were found groups in terms of time spent in INR range or adverse effects
Franke et al (2000)	Questionnaire survey of 263 GPs in Nottingham	GPs commonly had problems in drug dosing for certain groups of patients. CDSS could have helped in these situations

**Table 2.8 UK experience of CDSS within primary care settings (cont.)**

<b>Author</b>	<b>Type of Evidence</b>	<b>Main outcomes</b>
Frisher et al (2010)	Cohort study using a sample taken from the West Midlands portion of the General Practice Research Database. Of this sample 664,241 patients were assessed for the probability of recurrent stroke and risk and or benefit of treatment with aspirin	Use of decision analysis in practice was limited by the availability of reliable and valid data for many clinical conditions
Hobbs et al (1996)	Prospective controlled trial introducing PRIMED, a CDSS used in the management of hyperlipidaemia across 25 GP practices in Birmingham	GPs favoured the concept but cited technical problems. Greater integration of CDSS software and practice based handling systems was required
Hor et al (2010)	Cross sectional study with a questionnaire sent to 262 GPs in the West of Ireland to survey current use and GP attitudes towards adoption of CDSS	Despite favourable attitudes towards the adoption of CDSS many barriers were perceived that impeded incorporation into clinical practice
Johnson et al (2000)	Review article that described the background to Phase 3 of the PRODIGY project.	Phase 3 was being tested for a formal evaluation
Kroese et al (2005)	An evaluation of PharmDIS-e+ software a CDSS for predicting serum digoxin levels in patients. The study included 45 patients were recruited from 2 GP practices	PharmDIS-e+ software was able to predict serum digoxin levels with acceptable accuracy in most patients
Lewis et al (1996)	RCT conducted to examine the clinical effectiveness of providing GPs with the results of a self-administered computerised assessment of common mental disorders (PROQSY) in 681 patients that attend a GP practice in South London	The Group receiving PROQSY showed a modest clinical improvement at 6 weeks, but no difference at 6 months
Magnus et al (2002)	Questionnaire survey of GPs in four PCTs in the Nottingham area of the UK	A minority of GPs admitted to frequently overriding their drug interaction alert systems without properly checking them. The type of computer system used could affect whether alerts were overridden

**Table 2.8 UK experience of CDSS within primary care settings (cont.)**

<b>Author</b>	<b>Type of Evidence or Design</b>	<b>Main outcomes</b>
McCartney et al (1997)	Controlled trial to evaluate of feedback of GP's data on aspirin prescribing aimed at increasing coded aspirin prescribing in patients with heart disease	Feedback of prescribing practice can increase the proportion of patients with ischaemic heart disease receiving prescribed daily aspirin
McCowan et al (2001)	RCT to evaluate whether CDSS used in the management of patients with asthma improves clinical outcomes in 447 patients from 17 GP practices.	The use of CDDS that implemented guidelines during patient consultations could improve clinical outcomes for patients with asthma
Morris et al (2005)	Questionnaire survey of GPs to assess their views on the importance of specified patient safety features on clinical computer systems.	Patient safety was a key issue specifically in relation to deficiencies in features of clinical computer systems
Montgomery et al (2000)	Cluster RCT to investigate the effect of a CDSS and a risk chart on absolute cardiovascular risk, blood pressure, and prescribing of cardiovascular drugs in hypertensive 614 patients based in 27 GP practices in Avon	The CDSS did not confer any benefit in absolute risk reduction or blood pressure control and required further development and evaluation before use in clinical care could be recommended
Mitchell et al (2009)	National survey of selected NHS Trusts of nurses to examine nature and type of CDSS used including PCTs	Of the 141 different CDSS in use. 33 were used within primary care settings in either maintaining electronic patient records, triage, assessment, or prescribing
O'Cathain et al (2003)	To examine the consistency of triage outcomes by nurses using four types of computerised decision support software in NHS Direct	There were large differences in outcomes between nurses using different software systems to triage the same calls. If the variation was primarily attributable this could be eliminated using a single system
Oppenkowski et al (2003)	To establish and evaluate an external quality assessment scheme for warfarin dosing for users of a CDSS by analysis 12 months of clinical data from 10 primary care centres	Practices were successful in maintaining good therapeutic international normalised ratio control, with centres achieving 60% or higher time in range

**Table 2.8 UK experience of CDSS within primary care settings (cont.)**

<b>Author</b>	<b>Type of Evidence or Design</b>	<b>Main outcomes</b>
Pell et al (2003)	Retrospective analysis of patients receiving oral anticoagulant therapy in a single general practice compared to those managed in secondary care	INR control achieved in a general practice setting was superior to that in a dedicated hospital anticoagulant clinic
Purves and Sowerby (1996)	Interim report of Phase 1 of the PRODIGY project	PRODIGY was likely to be suitable as the basis of a practicable system for long term use. A continual process of improvement and updating to both guideline contents and supportive software would be necessary
Purves et al (1999)	Review article describing the background to PRODIGY and a summary of the first 2 phases of project	Details were provided of how Phase 3 would be developed
Robinson (2004)	Review article of the use of PRODIGY in practice	Nurses were able to use PRODIGY guidance as a resource to enhance both their personal and professional practice
Rousseau et al (2003)	Qualitative interviews with 13 participants from 5 GP practices (including 8 GPs) in the North East of England, part of a RCT involving 40 clinicians	Negative comments about CDSS significantly outweighed the positive or neutral comments
Shiach et al (2002)	An evaluation of achieving therapeutic INR targets in the control of warfarin in a community clinic supported by point of care testing (POCT) compared to a hospital laboratory testing in a RCT that involved 46 patients	It was possible to introduce a reliable and safe community anticoagulant service based on POCT monitoring
Short et al (2003)	Qualitative interviews with 15 GPs in the West Midlands to investigate sub-optimal prescribing of aspirin	GPs need support in assessing the risks and benefits of prescribing for patients with combinations of complicating risk factors which could be incorporated into a CDSS
Short et al (2004)	Qualitative interviews with 15 GPs in the West Midland to investigate barriers to the use of CDSS during consultations	Designers of CDSS for use in primary care consultations should account for the practical needs of users.

**Table 2.8 UK experience of CDSS within primary care settings (cont.)**

<b>Author</b>	<b>Type of Evidence or Design</b>	<b>Main outcomes</b>
Thomas et al (2004)	RCT based in 5 GP practices involving 762 patients to evaluate the use of a computerised psychosocial assessment that generated a report for the GP including patient-specific treatment recommendations	Only small benefits were found to be likely from using case finding followed by patient-specific guidelines to improve clinical management of common mental disorders in primary care
Toth-Pal et al (2008)	To explore the influence of a guideline-based CDSS how GPs managed cases of chronic heart failure	Using a guideline-based CDSS for GPs' own patient cases had an impact on the GPs' confidence in the diagnosis of chronic heart failure and their considerations about investigations and medications
Vadher et al (1997)	RCT based in a hospital but involved both in-patients and out-patients	CDSS was found to be safe and effective and improved the quality of initiation and control of warfarin treatment by trainee doctors
Van Schaik et al (2004)	Questionnaire survey of 30 GPs investigating the acceptance of a potential CDSS within primary care	70% of GPs intended to use the system with a 2 minute increase in consultation times, whilst 77% did not intend to use the system with a 5 minute increase in consultation time
Walton et al (1998)	Cross-over experiment with balanced block design involving 50 GPs in Oxfordshire to evaluate the effect of CAPSULE, a CDSS designed to support prescribing	CAPSULE significantly improved the quality of prescribing and improved compliance with guidelines. The system was easy to use and most of the participating GPs were likely to use it in practice
Wilson et al (2005)	Cluster RCT to evaluate a CDSS to support complimentary interventions in familial breast cancer in 57 GP practices compared to advice provided by a counsellors in regional centres	The CDSS could not be recommended for widespread use without further evaluation and testing in real practice
Xiao et al (2011)	Review article of an electronic health record to support methadone treatment incorporating CDSS by use of a web-based data entry system	A discussion of the potential of implementing a web-based data entry system incorporating elements of a paper prescription form whilst at the same time facilitating CDSS

One of the earliest published studies to evaluate CDSS within UK general practice was a prospective evaluation of the management of hyperlipidaemia involving 25 GP practices in the Midlands (Hobbs et al 1996). Although favouring the concept, users criticised technical problems and recommended that greater integration of CDSS with practice clinical systems was required. In addition uptake was lower than expected and prescribing, a key outcome measure, showed no significant alteration following system use. In contrast positive attitudes towards computerised prescribing support by GPs was reported by Walton et al (1998) from an evaluation of a CDSS prototype CAPSULE with 42 randomly selected GPs in Oxfordshire. This evaluation, based on 36 simulated cases constructed from real consultations, concluded that computerised support significantly improved the quality of prescribing, compliance with guidelines, was easy to operate and that most participating doctors would be likely to use it in practice.

In 1995 the NHS Executive commissioned the Sowerby Centre for Health Informatics at the University of Newcastle to research the acceptability of CDSS to GPs, its impact on prescribing habits and to address a range of other questions pertinent to the future development of general practice. An interim report suggested positive steps in the provision of drug and patient advice leaflets (Purves and Sowerby 1996). The research team adopted a rapid iterative methodology with NHS Executive, academic project team, GPs and the five leading GP computer suppliers collaborating to develop and improve the product known as PRODIGY (Purves et al 1999). The first phase involved GP system suppliers recruiting 137 GP practices and the second phase 183 GP practices with sites located in 61 of the then 91 Health Authorities in England. PRODIGY was launched in 1999, available free to all GPs, fully funded by the NHS and provided on screen advice about referral, investigations, specific non-drug advice, doctor / patient shared advice screens and the provision of condition specific patient information leaflets (Broderick 1999). However a subsequent evaluation of the system, using a randomised controlled trial within 60 GP practices in the North East of England showed there was no significant effect on consultation rates, patient outcomes or process of care measures including prescribing (Eccles et al 2002). In addition authors reported that the overall usage of the CDDS was low.

PRODIGY was eventually withdrawn in 2006 amongst reports that it had never been used by more than 10% of GPs and that it should not have received NHS funding (Bostock 2007).

PRODIGY was replaced with Clinical Knowledge Summaries (CKS) in a contract awarded to a consortium of the Sowerby Centre and EBSCO (an international medical publisher). In 2011 CKS became incorporated into the clinical work program of NICE.

A number of notable CDSS systems have been developed by the University of Keele to support disease management such as stroke and diabetes (Chapman 2007). In recent years a number of other commercial CDSS have been introduced offering a range of services particularly with drug information and prescribing support. Script-Switch<sup>®</sup>, a CDSS that links with GP clinical systems, in to provide at point of prescribing local formulary choices, advice on cost effective alternative medicines and messages reminding clinicians of any relevant information such as safety or effectiveness issues (Anon 2010a). In addition NHS primary care organisations were able to manage and locally author these messages and receive reports about uptake by individual GP practices and the resulting savings generated in prescribing. The Script-Switch<sup>®</sup> website reported that over 124 primary care organisations across the UK had commissioned the software on behalf of 5,500 GP practices (Anon 2011a).

#### **2.4.3.1 CDSS UK end user evaluations**

Evaluations of CDSS usage and perceptions of GPs provided a range of both positive and negative outcomes. A number of studies have provided some evidence that CDSS have improved outcomes for patients such as providing better drug dosing information in high risk groups compared to paper based resources (Franke et al 2000), in managing asthma (McCowan et al 2001) and in the use of aspirin in patients following a stroke (Short et al 2003). However some studies, although demonstrating either some or limited benefits, have recommended CDSS use without further testing or evaluation such as in cardiovascular risk management (Montgomery et al 2000), cancer screening (Emery et al 2000, Wilson et al 2005) and in supporting mental health conditions such as depression (Thomas et al 2004).

In an evaluation of a CDSS supporting the availability of electronic guidelines, concerns reported by GPs included the timing of the guideline trigger, ease of use of the system, and helpfulness of the content (Rousseau et al 2003). The authors concluded significant barriers existed to the use of complex CDSS for chronic disease by GPs. These included the relevance and accuracy of messages and flexibility for the GP to respond to other factors influencing decision making in primary care.



Short et al (2004) undertook qualitative interviews with 15 GPs in the West Midlands and reported on practical barriers to the use CDSS during consultations including limitations of practitioners' IT skills, a lack of understanding of the risk output of systems, concerns about communicating risk sufficiently well to patients and time constraints of using CDSS during consultation.

#### **2.4.3.2 Safety deficiencies and overriding of CDSS alerts**

The scoping review identified a number of evaluations of CDSS in the UK were focussed on not just end users such as GPs, but also key stakeholders such as GP clinical system suppliers, academics and primary care managers. These studies evaluated the safety of alerting systems provided by CDSS within GP clinical systems and the results are summarised in Table 2.9. A prominent feature of CDSS is the safety functionality of warnings and alerts and the ability for users to cross check prescriptions for known sensitivities, drug interactions and active ingredient duplications. In a questionnaire survey of 334 GPs in the Nottingham area 49 of the 220 respondents (22%) admitted to frequently or very frequently overriding drug interaction alerts without proper checking, reasons cited as the perception that the alerts were frequently irrelevant (Magnus et al 2002). Fernando et al (2004) described concerns with safety deficiencies of the CDSS alerts provided by the main GP clinical system suppliers in the UK and identified that all systems could fail to warn a GP in a situation where a warning was expected. Key features for improving safety and the quality of CDSS alerts have been suggested, such as the need to avoid spurious alerts (Avery et al 2005), making it difficult to override critical alerts (Avery et al 2005) and ensuring that software developers were made aware of the importance of human ergonomics in the design of hazard alerts (Avery et al 2007). Morris et al (2005) described the importance of safety alerts available from within GP clinical systems and that deficiencies included a lack of awareness of specific functions in relation to safety and in the level of training available to support the use of these functions.

**Table 2.9 Studies have evaluated the safety of alerting systems provided by CDSS within GP clinical systems**

Author	Design	Results	Outcomes
Magnus et al (2002)	Questionnaire survey of 336 GPs based in four PCTs in the Nottingham area of the UK to assess GPs' views on the relevance of information provided by alert systems. Response rate was 70%, analysis conducted on 220 replies.	22% (49 of 220) of GPs admitted to frequently or very frequently overriding drug interaction alerts without properly checking them. Potential reasons for overriding alerts included the perception that the alerts were frequently irrelevant.	A minority of GPs admitted to frequently overriding their drug interaction alert systems without properly checking them. The type of computer system used by GPs may have made it more or less likely to override alerts.
Fernando et al (2004)	Laboratory testing of 4 of the main GP clinical systems against a list of 18 theoretically derived scenarios related to safety drawn up by an expert panel via a 2 round Delphi Approach	None of the systems produced alerts for all 18 scenarios. In one scenario of prescriptions with similar drug names none of the systems warned for all 10 drug pairs considered	The safety features of the 4 systems that covered three quarters of UK general practices had clinically important deficiencies.
Avery et al (2005)	Two - round electronic Delphi survey, completed by an expert panel. The main outcome measure was percentage agreement of the panel members on the importance of the presence of a number of different safety features (presented as clinical statements) on GP computer systems.	90% or greater agreement on the importance of 32 (58%) statements. These statements, indicating issues considered to be of considerable importance, related to: computerised alerts e.g. the need to avoid spurious alerts and making it difficult to override critical alerts	The high level of agreement among the expert panel members indicated clear themes and priorities that needed to be addressed in any further improvement of safety features in primary care computing systems.
Morris et al (2005)	Questionnaire survey of 609 GPs based in six PCTs from the Midlands and North West England to assess GPs' views on the importance of specified patient safety features on their clinical computer system; their knowledge of the presence of specified safety features; previous training and perceived future training needs. Response rate was 64%, analysis conducted on 381 replies.	Although patient safety features were considered to be an important part of their clinical computer system by the vast majority of GPs, many were unsure as to whether the system they were using actually possessed some of these specific features. Some of the GPs believed in error that their computers systems would warn them about potential contraindications or if an abnormal dose frequency had been prescribed. Only 94 of the GPs (24%) had received formal training on the use of these specific patient safety features	Patient safety was an issue high on the agenda of this cohort of GPs. The importance of raising GPs' awareness of both the potential use and deficiencies of the safety features on their clinical computer systems and ensuring that appropriate training is available should not be underestimated.

**Table 2.9 Studies have evaluated the safety of alerting systems provided by CDSS within GP clinical systems (cont.)**

<b>Author</b>	<b>Design</b>	<b>Results</b>	<b>Outcomes</b>
Avery et al (2007)	Qualitative study using semi-structured interviews with 31 participants, representing a broad range of relevant disciplines and interest groups e.g. clinicians, computer system suppliers, drug database suppliers and academics with interests in health informatics	Participants identified deficiencies in current systems that pose serious threats to patient safety. To bring about improvements, providers need to supply clinicians with safe, accurate and accessible information for decision support.	Priorities included improving the knowledge base for CDSS, paying greater attention to human ergonomics in system design, improved staff training and the introduction of new regulations mandating system suppliers to satisfy essential safety requirements

### **2.4.3.3 CDSS and therapeutic blood monitoring**

One area where CDSS has been shown to provide clear benefits in terms of clinical management and improved patient outcome supported by robust evidence has been in therapeutic blood monitoring. In the UK, with the exception of a single study that reported on an evaluation of a CDSS designed to predict digoxin blood monitoring within 2 GP practices (Kroesse et al 2005), evaluations have centred on the effectiveness in the monitoring and dosing of one oral anticoagulant drug, warfarin. It is estimated that around one million patients in the UK receive oral anticoagulation medicines such as warfarin which is commonly indicated for use in the prevention of embolic stroke and transient ischaemic attacks in patients with atrial fibrillation (Matthey 2007). Once initiated subsequent doses of warfarin are adjusted dependant on prothombin time reported as an international normalised ratio (INR) which requires regular blood monitoring. Introduced in the 1980s manual algorithms to predict doses based on mathematical correlations were proving costly, laborious, and produced indifferent results when compared to those calculated using computers which were as reliable (Treharne - Jones et al 2005).

#### **2.4.3.3.1 Primary care anticoagulation management**

In the 1990s primary care based clinics in general practice were established to support the shift of clinical services from secondary care to primary care for a range of conditions and treatments including anticoagulation (Treharne Jones et al 2005). CDSS became available to support point of care testing (POCT) using commercial meters that measured INR using capillary samples of blood rather than sending venous samples of blood to a hospital clinic. Summarised in Table 2.10 are UK studies that established an evidence base for the effectiveness of CDSS in anticoagulation management in primary care.

Early studies (Pell et al 1993, Fitzmaurice et al 1996, 1998b) reported on the positive outcomes in anticoagulation management within general practice when compared to hospital based clinics in terms of the level of INR control. Following a similar design but including a larger number of patients (377 from 12 GP practices, Fitzmaurice et al (2000) further demonstrated that patients attending GP practice based clinics had a significant improvement in the proportion of time spent within INR ratio compared to those attending hospital clinics. In a later retrospective analysis of patients receiving warfarin from this study including new patients initiated on treatment (n = 452) Fitzmaurice et al (2001) compared INR management in a total of 122 patients managed in practice based clinics against 330 in hospital based clinics.

The authors reported no significant difference between the two groups in terms of percentage time in spent in INR range (69% practice based vs. 64% hospital based), recall or adverse effects. This resulted in the 'Birmingham model of oral anticoagulation management' comprising of near patient testing for INR measurement and CDSS to interpret the INR within practice nurse led primary care clinics.

Shiach et al (2002) reported the success in achieving therapeutic INR control in a community setting when compared with hospital laboratory testing but also patient satisfaction. They concluded it was possible to introduce a reliable and safe community anticoagulant service acceptable to medical and nursing staff and was popular with the patients. The need for accuracy in measuring INR led to the development of an external quality assessment scheme to ensure measurement of INR was consistent in different environments. Oppenkowski et al (2003) reported on the development and implementation of the first scheme for a specific CDSS, "BAP-PAC" in a 12 month evaluation of the management of 367 patients based in 10 GP practices in England. Practices were required to submit data on patients for external assessment at an academic centre. The results demonstrated that all practices using BAP-PC were maintaining good therapeutic INR control, with patients achieving 60% or higher time in range at and an average of 69%.

A further development in anticoagulation management was patient self-management using POCT. Fitzmaurice et al (2002) reported on the first randomised trial to compare routine primary care management of oral anticoagulation with patient self-management. Although it proved to be a more costly model the results showed patient self-management was as safe and effective as routine care. Following a larger multi-centre trial based in the Midlands, Fitzmaurice et al (2005) reported that with appropriate training, self-management was safe and reliable for a sizeable proportion of patients receiving oral anticoagulation treatment and that it may improve the time spent in the therapeutic range for patients with initial poor control.

**Table 2.10 UK studies of CDSS in anticoagulation management in general practice and the development of self-management**

<b>Author</b>	<b>Design</b>	<b>Results</b>	<b>Outcomes</b>
Pell et al (1993)	Retrospective analysis involving 32 patients receiving oral anticoagulant therapy in a single general practice and 123 patients and a dedicated hospital anticoagulant clinic in Fife, Scotland.	In 261 of the 1088 general practice appointments (24.0%) resulted in adjustment of the dose of warfarin compared with 726 of the 2828 hospital attendances (25.7%). In addition 51.6% of general practice appointments and 45.5% of hospital appointments, venous thrombotest INR results fell within the therapeutic ranges	The findings of this study suggested that INR control achieved in a general practice setting was superior to that in a dedicated hospital anticoagulant clinic
Fitzmaurice et al (1996)	Randomised trial involving 49 patients from 2 GP practices. Evaluation of CDSS for oral anticoagulation management by measuring proportions of patients adequately controlled defined as being within INR range.	Significant improvements were seen in INR control from 23% to 86% in the practice where CDSS was used. Mean recall times were significantly extended in the practice where dosing was managed by CDSS from 24 days to 36 days.	CDSS enabled safe and effective transfer of anticoagulation management from hospital to primary care. This model allowed improved patient outcomes in terms of level of control, frequency of review and general accessibility
Fitzmaurice et al (1998b)	Prospective evaluation of therapeutic and clinical control of patients using warfarin in 29 patients in a practice that had introduced a primary care clinic supported by CDSS	This study reported the first data from a long-standing clinic outside of a formal study. Twenty nine patients seen in 208 appointments with the mean percentage of patients within INR range was 72% at a cost to the practice of £1751 compared to £2290 if patients were seen at hospital.	CDSS in a nurse led clinic delivered oral anticoagulation monitoring that could enable the safe transfer of the majority of patients from secondary to primary care
Fitzmaurice et al (2000)	Randomised trial involving 377 patients from 12 GP practices in Birmingham. Patients randomised to attend 3 control practices (143) to receive hospital care or 9 intervention practices (224) to receive either hospital care (102) or practice based care (122)	Practice based care was in the form of a nurse led clinic offering POCT and with dosing managed by CDSS. The INR control in the intervention group was no different to the control group. The time spent within INR range in intervention group showed significant improvement compared to control group	Anticoagulant management using this model of care was at least as good as routine hospital follow up and could be generalised to primary care health centres in developed healthcare systems.

**Table 2.10 UK studies of CDSS in anticoagulation management in general practice and the development of self-management (cont.)**

Author	Design	Results	Outcomes
Fitzmaurice et al (2001)	Retrospective follow up of anticoagulation management in patients based in 12 GP practices in Birmingham. These practices were involved in a previous study (Fitzmaurice et al 2000). Outcome measures were INR control, adverse effects and recall frequency	There were no significant differences between practice-based and hospital-based populations in terms of the percentage time in range, (69% and 64% respectively). There was no difference between the two populations in terms of mean follow-up time (36 days in each group). There were no significant differences between groups for the number of clinical outcomes per patient.	This study confirmed that, within these practices, oral anticoagulation management was safe and effective using the Birmingham model.
Shiach et al (2002)	Randomised crossover trial involving 46 patients measuring success in achieving therapeutic INR targets in a community clinic was compared with hospital clinic laboratory	Time in INR target range between the groups was similar, with 60.9% on the POCT monitor and 59.3% with the clinic laboratory, with no significant difference in mean INR. Patient questionnaires showed greater satisfaction with community POCT monitoring.	Equal success of an anticoagulant service based on community POCT monitor whole blood testing compared with results from a long-established hospital anticoagulant clinic that was acceptable staff and popular with patients.
Fitzmaurice et al (2002)	Randomised trial involving 49 patients from 6 GP practices assigned to either self-management or routine primary care management of anticoagulation.	To test whether self - management was safe and effective in terms of INR control. No significant differences found between the two groups in INR control or adverse events. The cost of self-management was much higher £90 vs £425 / patient per year	This study was the first available evidence to show self-management was as safe as primary care management.
Oppenkowski et al (2003)	Analysis of 12 months of clinical data from 10 primary care centres using BAP-PC within an oral anticoagulation clinic of 367 patients based in 10 GP practices.	On average, patients spent 69% of time in the therapeutic range INR (range, 60-76%). In total, 33 adverse events were reported.	Practices were successful in maintaining good therapeutic INR control, with centres achieving 60% or higher time in range. Data extraction from practices was used in the development of an external eight point quality assessment scheme

**Table 2.10 UK studies of CDSS in anticoagulation management in general practice and the development of self-management (cont.)**

Fitzmaurice et al (2005)	Multi-centre open randomised trial in the Midlands including 617 patients from 49 from GP practices identified to determine effectiveness of self-management compared to routine care in patients on long term anticoagulation.	In 337 patients randomised to the intervention group of whom 242 were successfully trained for self-management. 280 patients were randomised for routine care. There was no significant difference between groups in terms of time spent in INR range or adverse events. Self-managed patients with poor control before study showed an improvement and this was not seen in the other group.	Following appropriate training self-management was found to be safe and a reliable model of anticoagulation management.
--------------------------	---	---	---



#### **2.4.3.4 Other supporting literature**

Thirty items of additional supporting literature about CDSS and references to wider aspects of health informatics were collated. This information provided both historical and conceptual aspects to developments in the field. Data was identified in the form of book chapters, articles and papers written by academic experts.

#### **2.4.3.5 Website Reviews**

Two NHS websites and eight websites of commercial CDSS suppliers including GP clinical system suppliers were searched for evidence in relation to the availability of CDSS.

##### **NHS Connecting for Health**

Evidence was found in relation to CDSS however this was aimed to support the use of CDSS as part of a wider roll out of proposed electronic prescribing within secondary care in the form of guidance and policies. Fourteen "world view reports" authored by Professor Dennis Protti, between February 2005 and August 2006, concerning IT in healthcare were reviewed.

##### **The National Institute of Clinical Excellence**

Evidence was identified from the NICE shared learning section of the website about CDSS developed by the University of Keele, to support the implementation of NICE hypertension guidelines (NICE 2009). In addition a 2005 press release (NICE 2005) and a 2005 progress report (Phillips and Cox 2005), were identified that described a proposed feasibility study to look at whether existing NICE methodologies such as Technology Appraisals (TAs) could be applied to an evaluation of CDSS.

##### **Commercial providers of CDSS**

The websites of known commercial organisations that provided CDSS in the UK, First Databank<sup>®</sup>, Script-Switch<sup>®</sup> and INR-star<sup>®</sup> were searched. In addition the websites of GP clinical system providers EMIS, INPS (Vision), Micro-Test, iSOFT and SystmOne all confirmed the provision of CDSS to support GPs in the provision drug databases to include automatic drug related warnings and alerts. In addition the GP clinical system suppliers offered through partnership programs a range of external web-based applications to support a variety of functions to support the running general practice including the national GP contract. A summary of evidence of the availability of CDSS from these websites is shown in Table 2.11.

**Table 2.11 Summary of the availability of CDSS from commercial providers in the UK**

<b>Commercial Organisation</b>	<b>Date website accessed</b>	<b>Evidence identified</b>
First Databank	December 2011	The CDSS within the “Multilex Drug Data File “ provided by Firstdata Bank provided functionality to check when medication was about to be prescribed or dispensed against information held in an electronic patient held record as a real time alert. The alerts included drug interactions, drug food interactions, sensitivities, contraindications, drug doubling, therapeutic doubling similar names and dose range checking.
Script-Switch <sup>®</sup>	May 2011	The software application was in use in 5,500 GP practices in the UK, commissioned by 124 NHS primary care organisation. In general outcomes were expressed in cost savings in relation to prescribing budgets. In terms of additional evidence this was available in the form of PCT case studies and one survey of 106 GP users conducted by a market research company on behalf of the company On-line demonstrations were viewed that showed how the application worked within each of the major GP clinical system suppliers.
INR Star <sup>®</sup>	December 2011	The software application was in use in nearly 2000 locations in the UK and abroad. A brochure was downloaded that described features of the CDSS, benefits, training and support for NHS commissioners and providers in planning and delivering anticoagulation services
GP Clinical System Suppliers; EMIS, INPS (Vision), Micro-Test, iSOFT and SystmOne	December 2011	All of the GP clinical system suppliers provided details of in-built CDSS to support prescribing as drug related warnings and alerts. A wide range of platform sharing with external software applications was available from each system, but all suppliers were linked to a national framework to support the GMS contract. Links were available to known CDSS suppliers such as INR Star <sup>®</sup> and Script-Switch <sup>®</sup> .

#### **2.4.3.6 Personal Communication**

Personal communication with the lead researcher (NC) and representative of a UK commercial provider of CDSS took place in 2011 as one informal meeting with one representative and a telephone conference call with two other representatives from the same commercial provider. General details of CDSS usage and availability in the UK were discussed. Information regarding the provision of CDSS by this provider was already available from the company website. During these discussions no additional information was made available such as pending or unpublished trials or studies including randomised controlled trials or qualitative evaluations.

### **2.5 Discussion**

The scoping review methodology resulted in the development of a catalogue of literature concerning the use CDSS in primary care. The studies and articles included in the final analysis came from a number of countries, with the majority from the USA and UK. Advances in information technology, particularly within primary care over the last 30 years has meant computers are widely available and are routinely used for nearly all healthcare activities within UK general practice. Experience of CDSS was identified in a wide range of clinical areas such as disease management, drug dosing, therapeutic control and prescribing. In addition the clinical systems used by GPs in the UK all provided CDSS in the form of alerts and warnings to allergies and drug interactions and additional functionality to allow access to a range of software applications.

A specific area where positive outcomes were identified was in the development of CDSS to support primary care based anticoagulation management. In addition this has further been supported by the inclusion within the GMS contract as an enhanced service specification (NHS Employers 2009). This service requires GP practices to demonstrate adherence to a wide range of clinical and performance measures including an annual review to include details of any CDSS used and arrangements for internal and external quality assurance. In addition anticoagulant prescribing within the service specification is supported by guidelines devised by the British Society of Haematology. These guidelines have highlighted the safety and effectiveness of CDSS in supporting warfarin dosing and have recommended the use of CDSS over manual dosing (Keeling et al 2011). In addition under the enhanced services specification GP practices are required to subscribe to a national external quality assessment service (NEQAS) that provides assessments of tests of blood coagulation for a range of clinical indications including systems designed for point of

care testing (POCT). Matthey (2007) has described a number of UK based models to support anticoagulation management supported by the availability of both commercial POCT meters and CDSS such as 4S Dawn<sup>®</sup>, Hirumed RAID<sup>®</sup> and INRstar<sup>®</sup>. In terms of INRstar<sup>®</sup> the website, reported that this application was the UK market leader for anticoagulation management and was being used in over 2,000 clinics in the UK and abroad (Anon 2011b). The CDSS Script-Switch<sup>®</sup> was reported to be installed in over 5,500 UK GP practices (Anon 2011a). However evidence from published trials of evaluations, or the views and experiences of GPs in using this CDSS were as not available. The website provided evidence of case studies from individual PCTs and substantial cost benefits to the NHS reported as savings against primary care prescribing budgets.

Key themes that emerged from studies and evaluations of the CDSS evidence base from the UK, USA and Australia included safety deficiencies in systems (Fernando et al 2004, Avery et al 2005, 2007, Sweidan et al 2010), over-alerting, ignoring or and the overriding of alerts (Magnus et al 2002, Ahearn et al 2003, Weingart et al 2003, Isaac et al 2009) and the need for developers of CDSS to engage with the end users in the design of CDSS (Avery et al 2007, Robertson et al 2011). In addition some of negative outcomes of CDSS usage were also apparent across the UK and USA to include poor usage (Rotman et al 1996, Eccles et al 2002, Judge et al 2006), adherence to guidelines (Tierney et al 2003, Rousseau 2003) and patient outcomes (Montori et al 2002, Eccles et al 2002).

These outcomes correlated with of the evaluations of the literature in relation to CDSS. Coiera et al (2006) reviewed the literature in relation to the safety and quality of CDSS in both primary and secondary care including the UK, USA and Australia. Although the authors reported that CDSS was a potent intervention to improve the quality, safety and the effectiveness of clinical decisions uptake levels remained low. Barber (2004) examined the experience in the UK and USA in the development of IT systems in both primary and secondary care. CDSS was described in relation to doctors' performance, patient outcomes, managing therapeutic control of drug concentrations and also in helping patients in managing screening or treatment. The author critiqued the various CDSS models suggesting a lack of evidence that had demonstrated improved patient outcomes and evaluations of the field were of a limited quality and could not be generalised.

## **2.6 Limitations**

There were a number of limitations to this scoping review. The main issue was the lack of time and available resources in terms of being able to actively engage further particularly with stakeholders. There was only one lead researcher (NC) and no additional staff or resources were available so the scope was limited to healthcare database searches, interrogation of known websites and informal discussions with informants from a specific stakeholder. Only one commercial CDSS supplier was engaged with and research team were not able to engage with representatives from other providers particularly GP clinical system suppliers or indeed from with stakeholder groups such as NHS IT management or from the end users of CDSS i.e. GPs. Other alternative options which could have been explored included the use of existing networks, which could have included medicine management teams or primary care commissioners, based on the reported usage and availability of CDSS applications such as Script-Switch® and INRstar®. In addition time was not available to consider attending conferences in relation to commercial providers of CDSS and or wider aspects of NHS information technology provision either at a local level or with Department of Health. In addition the views and experiences of patients would have been particularly useful not just in their views of the use of IT but especially of how CDSS would benefit them during consultations or in other aspects of their healthcare needs.

## **2.7 Further work**

A number of gaps in the literature in relation to CDSS use in the UK were identified such as an understanding of current usage, system types, available and specific features and characteristics. Although the use of CDSS underpinned data transfer to support the GMS contract no evidence was available on the actual awareness or use of additional software applications that were available through GP clinical system suppliers. The lack of independent trials or evaluations of Script-Switch® could also form the basis of additional research. Although the company provided reports on usage, including acceptance rates of messages or alerts this data was only available to NHS medicines management teams for localised use. The views or opinions of this CDSS could be sought from not only end users such as GPs but also from the medicine management teams that author the content of these messages.

Although INRstar® was identified as an established CDSS provider no evaluations had been published on in terms of effectiveness or patient outcomes across larger geographical areas or indeed at a national level to include the use of other providers of CDSS in anticoagulation management.

Xiao et al (2011) was the only study that explored the potential of developing and implementing a web based health record that incorporated elements of a paper prescription form whilst at the same time facilitating CDSS in assisting GPs in managing the use of drugs used to treat substance misuse, namely methadone. The authors explored the concept model approach for the use of international standards including SNOMED CT, and although described a lack of enthusiasm from GP clinical system suppliers, they reported that this model could be extended to other drugs. This raises the potential to consider other areas for research where CDSS could support GPs such as in primary care management is dependent on the reliance of input from either secondary care advice from clinicians or the need for the results of pathology or other monitoring arrangements.

In 2010 the Government White Paper “Equity and Excellence, Liberating the NHS” outlined plans to transfer the commissioning of the £80 billion NHS primary care budget to newly formed GP consortia (Department of Health 2010). GP consortia became responsible for the management of the national drugs bill alongside planning if, how and where traditional hospital based activity was to be provided in primary care. This has been described as an opportunity to change the arrangements for either the administration or prescribing of specialist drugs avoiding the need for patients to attend hospital clinics with new services available within a GP surgery, community hospital or primary care based clinic (Anon 2012). One specific area where there has been no published evidence is the availability of CDSS to support GPs in managing the prescribing of either high risk drugs, drugs initiated by hospital specialists or in areas where patient care is shared by both primary and secondary care.

## **2.8 Conclusion**

This scoping review highlighted a range of issues with regards to the use of CDSS within primary care in the UK. Despite of the reported widespread availability of CDSS the available evidence in terms of quality such as in randomised controlled trials was limited and was mainly found in supporting anticoagulation management. Key aspects that emerged both in the UK and from abroad were problems associated with low usage, over-alerting, concerns with safety and the need for improvements such as in standards and in developing future CDSS based on engaging closely with end users.

## **Chapter 3**

**An exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice**

### **3.1 Specialist drugs and shared care**

Integrating primary and secondary care services was a direction introduced into the NHS in the early 1990s through the concept of “shared care” and the development of schemes intended to address many of the difficulties of the referral system especially in the long-term management of chronic disease (Hickman et al 1994). Such schemes were based around the joint participation of hospital consultants and GPs in the planned delivery of care and an enhanced exchange of data over and above normal referral and discharge letters. A wide variety of such schemes soon evolved across the UK encompassing a range of long term conditions such as asthma, diabetes and hypertension. Hickman et al (1994) characterised schemes identified from two surveys into six models of care including community clinics run by specialists and the use of patient held shared care record cards. Other models included the use of computer assisted shared care with data shared across secondary care and GP practice systems and the early piloting in Derbyshire of the use of electronic mail. Hampson et al (1996) reviewed the supporting literature to identify practice exemplars that could be adapted for local use. One important aspect identified was communication between primary and secondary care in addition to shared prescribing and disease management. The authors suggested that the most effective system or models of shared care had yet to be established and that although the available literature described practice exemplars communication between professionals continued to be a problem.

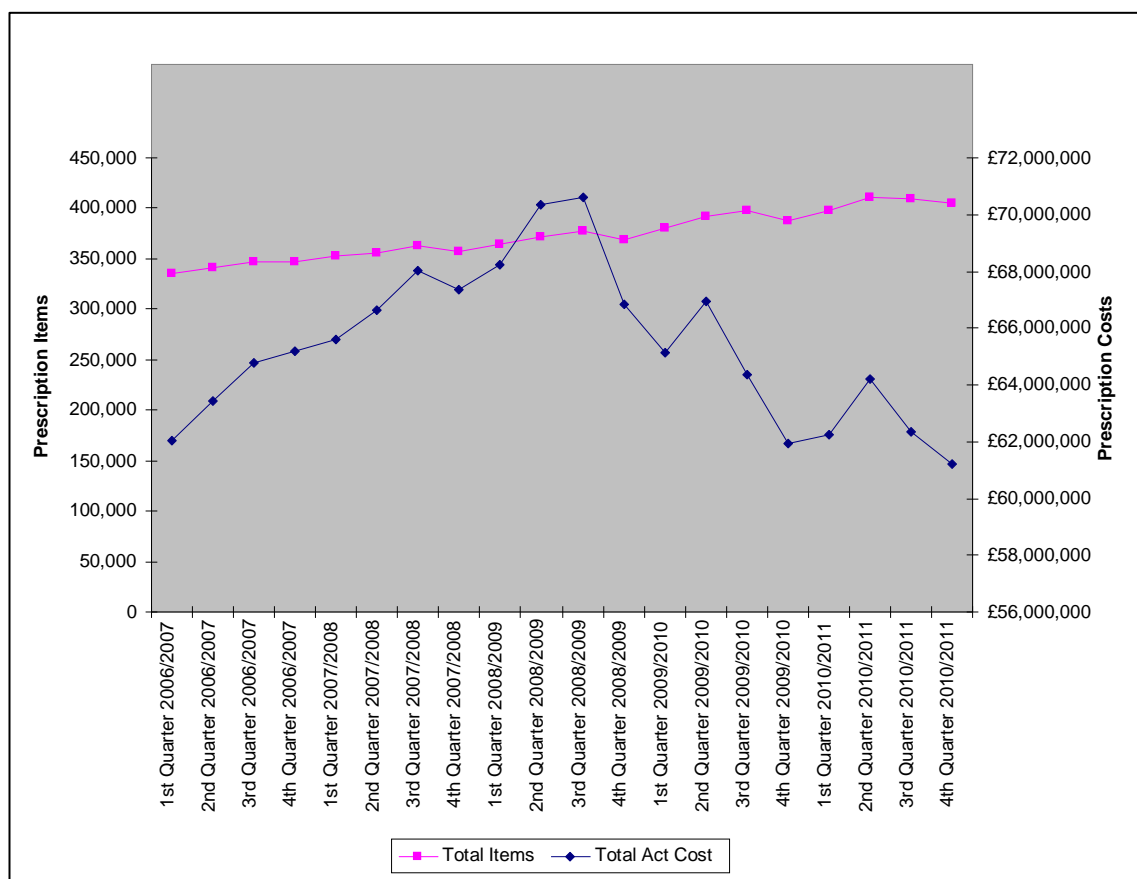
Despite the huge financial investment in the NHS and primary care, the evidence to support shared care has remained limited. A systematic review of 20 studies of shared care interventions including 6 from the UK, reported that apart from prescribing there was insufficient evidence to demonstrate significant benefits of shared care in disease management due to methodological shortcomings and the lack of evidence to support the widespread introduction of shared care services (Smith et al 2009). The concept of shared care was not just restricted to chronic conditions such as asthma or diabetes, which were routinely managed by GPs in primary care, but also to specific drugs of a specialist nature. Specialist drugs have been defined as having “significant pharmacological complexity and / or rarity of use to make the prescribing of the medicine relatively uncommon in the community” (Greater Manchester Medicines Management Group 2011 p2). In addition patients receiving these drugs may require complex monitoring requiring specialist knowledge for interpretation and management.



Guidance from the NHS Management Executive (EL (91)127) outlined core principles and responsibilities associated with prescribing particularly with the transfer of treatment between secondary and primary care. Where this involved new or rarely prescribed treatments including unlicensed drugs, shared care arrangements were proposed in the form of a protocol outlining responsibilities for both hospital and primary care clinicians (Department of Health 1991). Prescribing any drug carries significant risk with regards to side effects and adverse reactions; however there is also the associated clinical and legal responsibility that will rest with the clinician who signs the prescription (Khambh and Barnick 2007). In general, once a patient leaves hospital, clinical care is transferred wholly to the GP with any appropriate support and advice. If the patient is receiving a specialist drug, consideration needs to be given that not all GPs will have the relevant experience or specialist expertise to undertake full clinical and legal responsibility for prescribing (Khambh and Barnick 2007). The aim of a shared care protocol is to provide clear specific information regarding the specialist drug and to set out individual clinicians' roles and responsibilities.

### **3.1.1 Specialist drugs: Primary care prescribing trends**

Avery (2010a) has described the increased complexity in prescribing faced by GPs over the last twenty years with key contributory factors including managing larger numbers of patients on multiple medications and having to learn about the safe and effective management of high-risk drugs. This has required improvements in systems for follow-up and monitoring of patients in general practice. In recent years there has been an increasing level of prescribing of specialist drugs by GPs in primary care, factors which contributed to this have included patient convenience, better risk management, a reduction in secondary care workload (e.g. out-patient appointments) and the transfer out of prescribing expenditure (Anon 2008). Electronic prescribing analysis and cost tabulation (ePACT) data provides detailed information on a range of cost and volume derived indices to include individual drugs or drug groups at prescriber, practice, or NHS organisational level. In addition a number of prescribing indicators are available which have been specifically developed to allow practice comparison and are widely used by prescribing management teams. One indicator is based on the prescribing profile of designated specialist drugs. Figure 3.1 represents quarterly prescribing rates and expenditure on all specialist drugs in primary care (NHS Prescription Services 2012).



**Figure 3.1 Quarterly prescribing rates and expenditure on all specialist drugs in primary care between 2006 / 07 and 2010 / 11 in England.**

During this period, annual prescription items increased by 252,148 (18%) with annual expenditure decreasing by 2.1%. Total prescription items in 2010 / 11 amounted to just over 1.6 million at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill.

Table 3.1 lists the top 10 specialist drugs prescribed in England during 2010 / 11 by cost (NHS Prescription Services 2012). The highest expenditure by drug type was £80.4 million (32.2%) on the gonadorelin analogues busserelin, goserelin, leuprorelin, histrelin and triptorelin; followed by £65.7 million (26.3%) on the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus.

**Table 3.1 Top 30 Specialist Drugs prescribed in primary care (GPs) by cost in England 2010 / 2011**

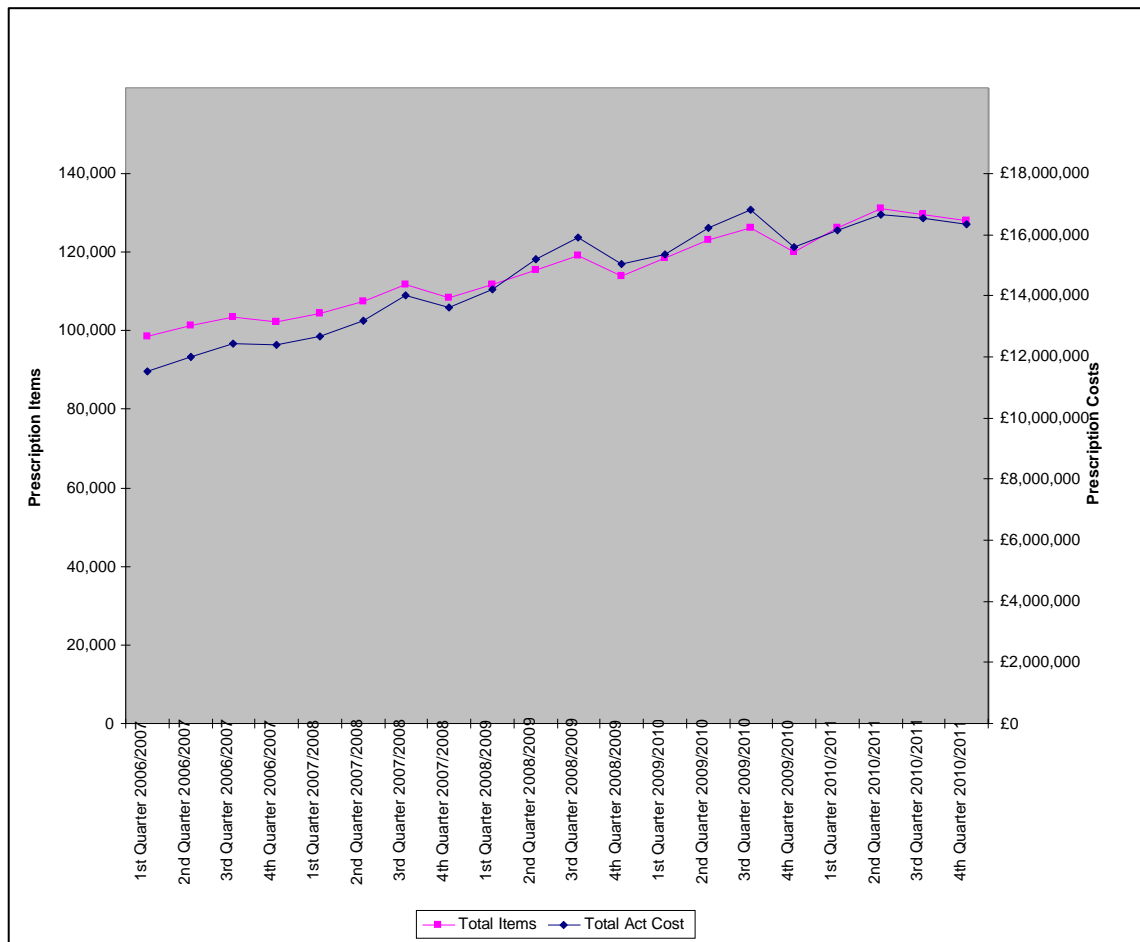
BNF Name	Total Items	Total Act Cost
Zoladex <sup>®</sup> LA Implant 10.8mg SafeSystem	124,048	£29,104,469
Goserelin Acetate Implant 10.8mg	105,815	£24,852,565
Mycophenolate Mofetil Tablets 500mg	104,075	£15,122,265
Tacrolimus Capsules 1mg	53,327	£9,863,894
Prostap <sup>®</sup> 3 Depot Injection 11.25mg	45,688	£9,573,959
Prograf <sup>®</sup> Capsules 1mg	49,553	£9,272,251
Genotropin Injection 12mg	6,371	£6,113,058
Saizen <sup>®</sup> Click Easy Injection 8mg	8,120	£5,411,801
Leuprorelin Acetate Injection 11.25mg	24,917	£5,211,130
Dornase Alfa Solution 2.5mg / 2.5ml Ampoule	9,382	£4,928,483

Table 3.2 lists the top 10 specialist drugs prescribed in England during 2010 / 11 by prescription volume (NHS Prescription Services 2012). Commonly prescribed specialist drugs include the hormone antagonist goserelin (Zoladex<sup>®</sup>) and the anti-androgen agent bicalutamide (Casodex<sup>®</sup>); both used in advanced prostate cancer, the immunosuppressant drugs mycophenylate (Cellcept<sup>®</sup>), tacrolimus (Prograf<sup>®</sup>) and the anti-rheumatic agent leflunomide (Arava<sup>®</sup>).

**Table 3.2 Top 30 Specialist Drugs in primary care (GPs) by volume in England 2010 / 2011**

BNF Name	Total Items	Total Act Cost
Zoladex <sup>®</sup> LA Implant 10.8mg SafeSystem	124,048	£29,104,469
Bicalutamide Tablets 50mg	107,945	£734,205
Goserelin Acetate Implant 10.8mg	105,815	£24,852,565
Mycophenolate Mofetil Tablets 500mg	104,075	£15,122,265
Bicalutamide Tablets 150mg	86,048	£1,276,177
Leflunomide Tablets 20mg	65,660	£4,049,922
Leflunomide Tablets 10mg	61,888	£4,126,835
Tacrolimus Capsules 1mg	53,327	£9,863,894
Zoladex <sup>®</sup> Implant 3.6mg SafeSystems	50,962	£3,155,768
Prograf <sup>®</sup> Capsules 1mg	49,553	£9,272,251
Decapeptyl SR Injection 11.25mg	12,290	£2,355,662

As a drug group the four immunosupresant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus accounted for 31.7% of all specialist drugs prescribed, making these the most frequently issued by GPs in primary care. Quarterly prescribing rates and expenditure for these four drugs in England are shown in Figure 3.2 (NHS Prescription Services 2012).



**Figure 3.2 Quarterly prescribing rates and expenditure for the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus in England between 2006 / 07 and 2010 / 11**

During this period, annual prescription items for these four drugs rose by 109,442 (27.0%) with annual expenditure up by £17,314,418 (35.8%). These four drugs are licensed for the prophylaxis of acute organ rejection (renal, hepatic or cardiac) with ciclosporin also indicated in bone marrow transplantation, nephrotic syndrome. However specialists may also recommend these drugs in number of unlicensed conditions, such as ciclosporin in acute ulcerative colitis or mycophenolate in rheumatic disease (Joint Formulary Committee 2014).

### **3.1.1.1 Data limitations**

The specialist drugs list is maintained by NHS Prescription Services and included 90 drugs as of the last quarter (Oct – Dec 2011), and although periodically reviewed is not exhaustive. With area prescribing committees or equivalent forums basing drug policy on local health economies there may be variation in which specialist drugs are recommended for use only in secondary care or those suitable to be prescribed by GPs. For example the “traffic light classification” produced by Derbyshire Medicines Management Forum included 147 drugs, 105 classed as either “red”; where prescribing responsibility was retained in secondary care and 42 as “amber” where drugs were designated as suitable for primary care prescribing under a shared care protocol (Anon 2010b). In addition only 49 of these drugs (41 red, 8 amber) were included on the specialist drug data base maintained by NHS Prescription Services.

## **3.2 Organ transplantation**

In 1933, the first real attempt at transplanting a human kidney to a human recipient was performed in Russia, (Klintmalm 2004). Interest soon grew into transplant immunology culminating with the first ever successful human kidney transplant performed in 1951. It was in 1971 that scientists identified ciclosporin as having immunosuppressant properties (Bryan 2008). The drug transformed organ transplantation with one year survival of kidney transplants soon rising to 80%. With further advances in technology heart, heart and lung, and liver transplants became more widespread and successful. The expanding immunosuppressant market meant that, in the 1980s and 1990s, pharmaceutical companies became more interested in developing alternatives to ciclosporin, including combining treatment with new agents.

Organ transplantation services are available from 32 specialist centers spread across the UK. Table 3.3 shows all organ transplantations conducted in the UK by organ type between 2008 and 2013 (adapted from NHS Blood and Transplant 2013). The total number of organ transplants carried out each year has steadily increased from 3516 in 2008 to 4210 in 2013. Kidneys were by far the commonest organ transplanted accounting for 67% of all procedures during 2013.

**Table 3.3 Organ transplantations conducted in the UK by organ type 2008 – 2013 (adapted from NHS Blood and Transplant 2013)**

<b>Organ Transplant</b>	<b>2008 / 09</b>	<b>2009 / 10</b>	<b>2010 / 11</b>	<b>2011 / 12</b>	<b>2012 / 13</b>
<b>Deceased donor (DD) transplants by organ type</b>					
<b>Kidney</b>	<b>1403</b>	<b>1482</b>	<b>1502</b>	<b>1599</b>	<b>1750</b>
Pancreas	54	40	41	37	38
Kidney / Pancreas	152	160	156	173	166
Pancreas Islets	3	13	13	30	30
Heart	129	121	131	141	142
Lung (s)	143	145	169	175	188
Heart / Lung	3	5	3	5	3
Liver / Lobe	651	666	668	726	775
Other (Multi-Organ)	24	21	16	27	21
<b>Total DD transplants</b>	<b>2562</b>	<b>2563</b>	<b>2699</b>	<b>2913</b>	<b>3113</b>
<b>Living donor (LD) transplants by organ type</b>					
<b>Kidney</b>	<b>927</b>	<b>1038</b>	<b>1021</b>	<b>1009</b>	<b>1066</b>
Liver	27	20	21	38	31
<b>Total LD transplants</b>	<b>954</b>	<b>1058</b>	<b>1042</b>	<b>1047</b>	<b>1097</b>
<b>Total organ transplants</b>	<b>3516</b>	<b>3711</b>	<b>3741</b>	<b>3960</b>	<b>4210</b>

### **3.2.1 Immunosuppressant drugs**

These agents are used to suppress rejection in organ transplant recipients and to treat a variety of chronic inflammatory and autoimmune diseases (Joint Formulary Committee 2014). In solid organ transplantation the principal aim of immunosuppression is to promote organ survival through the prevention of acute rejection. Immunosuppression is required for as long as the transplanted organ functions; if it is stopped, then rejection occurs and the organ is lost (Watson and Dark 2012). Immunosuppression is normally given as a combination of drugs each with different sites of action with regimens varying on the perceived immunosuppressive challenge that the transplanted organ poses; with more powerful immunosuppression used where the risk of rejection is greater.

In the UK a number of drugs are available for use in transplantation such as the antiproliferative agents (e.g. azathioprine, mycophenolate), corticosteroids (e.g. prednisolone); calcineurin inhibitors (e.g. ciclosporin, tacrolimus); non-calcineurin inhibitors (e.g. sirolimus); mono-clonal antibodies (e.g. basiliximab) and immunoglobulins (e.g. rabbit antithymocyte) (Joint Formulary Committee 2014). In 2004, NICE guidance made a number of recommendations on the use of specific drugs in managing organ transplantation including recommendation for the use of some of these drugs in unlicensed indications (NICE 2004).

### **3.2.2 The National Reporting and Learning Service**

The National Reporting and Learning Service (NRLS) was one of three divisions of the National Patient Safety Agency (NPSA). The NPSA was an arm's length body of the Department of Health, established in 2001 with a mandate to identify patient safety issues and find appropriate solutions. Table 3.4 lists medication incidents by stage of medication process in both primary and secondary care for the period 2005 – 2010 in relation to ciclosporin, mycophenolate, sirolimus and tacrolimus (NPSA personal communication 2011). Of the total 1103 incidents 282 (25.5%) were directly related to prescribing, 11 of which occurred in primary care. In addition to this 44 incidents were classed as moderate, 1 as severe and 2 resulted in fatalities.



**Table 3.4 Medication incidents involving ciclosporin, mycophenolate, sirolimus and tacrolimus by stage of medication process reported via the NRLS between 2005 – 2010 (NPSA 2011)**

	Community Hospital	General / Acute Hospital	Mental Health Unit / Facility	Not applicable	Other	Primary Care Setting	Public place (specify)	Residence / Home	Social Care Facility	Unknown	Total
Administration / supply of a medicine from a clinical area	3	495	5	1	1	1	0	3	1	0	510
Advice	1	12	0	0	0	0	0	1	0	0	14
Monitoring / follow-up of medicine use	0	24	1	1	1	1	0	2	0	1	31
Preparation of medicines in all locations / dispensing in a pharmacy	2	159	0	0	3	26	1	3	0	1	195
Prescribing	4	259	1	1	1	11	2	2	0	1	282
Supply or use of over- the-counter (OTC) medicine	0	8	0	0	1	0	0	0	0	0	9
Other	0	57	1	0	0	3	0	1	0	0	52
<b>Total</b>	<b>10</b>	<b>1014</b>	<b>8</b>	<b>3</b>	<b>7</b>	<b>42</b>	<b>3</b>	<b>12</b>	<b>1</b>	<b>3</b>	<b>1103</b>

### **3.2.3 Generic prescribing**

In recent years patent expiry in recent years of three immunosuppressant drugs, ciclosporin, mycophenolate and tacrolimus has allowed the introduction of generic formulations (Johnston 2011). The introduction of both new formulations of tacrolimus and less expensive generic formulations has had a profound effect not just on the potential savings in drug costs but the associated risks and hazards with their use. In January 2009 the MHRA released a safety warning highlighting that medication errors with Advagraf® and Prograf® had been reported in seven European Union countries; with most reports from the UK (MHRA 2009). These reports fell into three categories, prescribing errors by either hospital doctors or GPs, dispensing errors at pharmacies or administration errors. In addition in some cases these errors resulted in patients being dosed incorrectly, leading to serious adverse reactions including acute rejection of transplanted organs.

Generic products are not licensed on the basis of clinical assessment in the relevant patient group but on bioequivalence assessment in healthy volunteers (Johnston 2011). Ciclosporin was introduced in the 1970s and is well established as a critical dose drug where brand prescribing and dispensing is recommended. With the growing numbers of generic oral tacrolimus products and the increased potential for inadvertent switching between these products the MHRA in the UK recommended that prescriptions for oral tacrolimus products be written by brand name only (MHRA 2010). In 2012 the MHRA issued a further alert following reports that graft rejection reactions and tacrolimus toxicity had resulted from a small number of unintended switches between products, and that where a prescriber intended to switch between any tacrolimus brand, careful medical supervision and therapeutic monitoring would be required (MHRA 2012). The annual cost of treatment following transplantation is around £5,000 per year, and higher in some cases depending on choice and combinations of agents used. Figure 3.3 shows the costs of originator brands and current generic formulations of tacrolimus, ciclosporin, sirolimus and mycophenolate available in the UK by manufacturer (MIMS 2014).

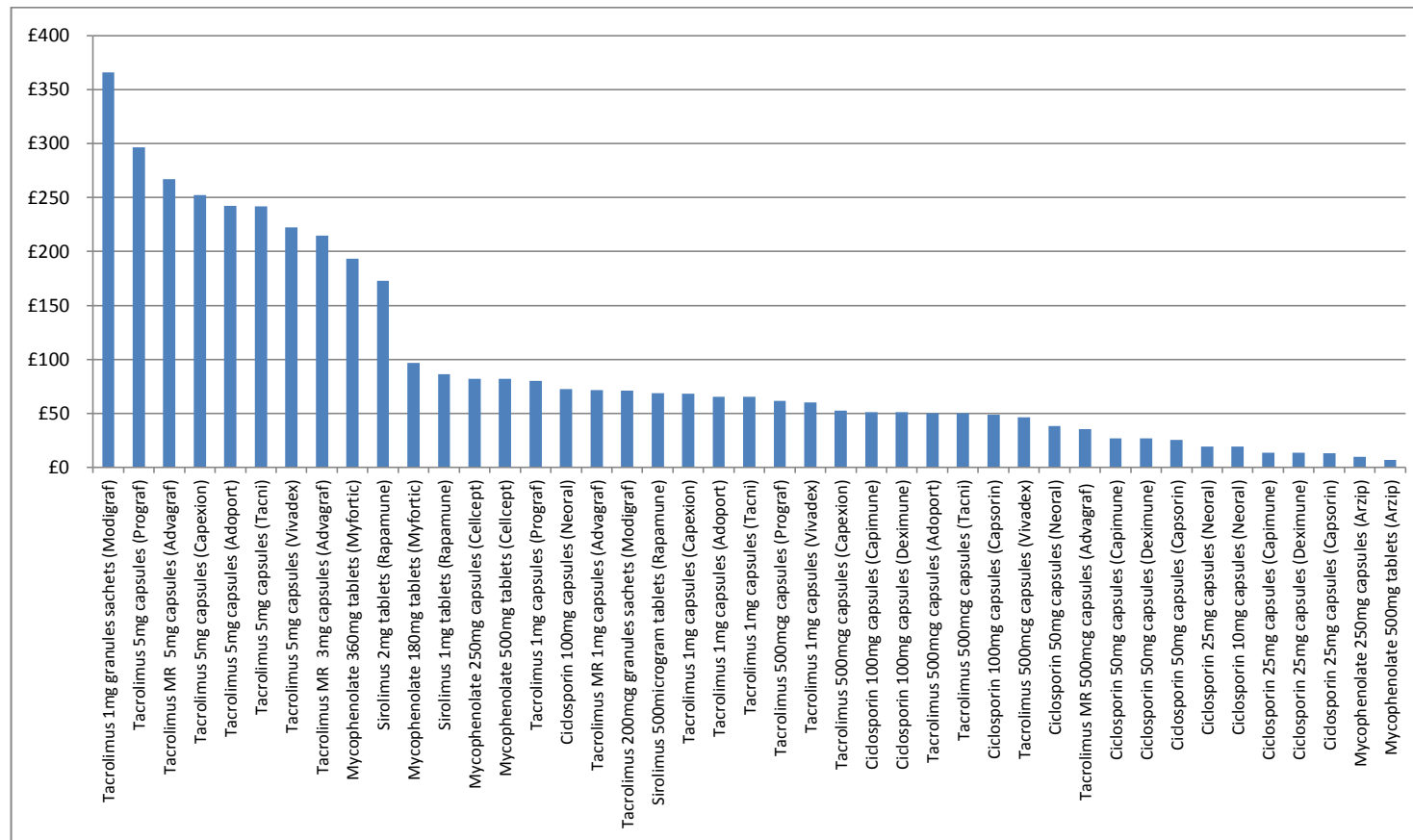


Figure 3.3 The cost by pack of all oral formulations of tacrolimus, ciclosporin, sirolimus and mycophenolate available in the UK.

### **3.3 Shared care protocols**

Six UK studies have either evaluated the characteristics of shared care protocols or the attitudes or views of clinicians towards their use and these are summarised in Table 3.5. Overall these studies have shown that despite the best attempts to develop and implement shared care protocols to support the use of specialist drugs these efforts have been in vain particularly from the perspectives of GPs. Key barriers to implementation have included the lack of GP involvement in their development (Gerada and Tighe 1999, Duggan et al 2001, Crowe et al 2009), and the general quality of shared care protocols including a lack of standards and availability (Duggan et al 2001). Lilife et al (2006) investigated the views and perceptions of GPs and specialists about the potential for shared care in the management of patients with dementia. Broad themes identified as barriers to successful implementation included risk reduction or avoidance, and concerns about competency and resources for shared care. In addition the authors described resistance from GPs in accepting shared care protocols citing issues in relation to time constraints and practice workload. Salt et al (2005) also highlighted concerns with the level of training that GPs received in managing conditions that required the use of specialist drugs.

Horne et al (2001) reported that GPs would be more likely to participate in shared care prescribing if they felt hospital doctors were supportive and more understanding of their position. In addition the authors identified key quality indicators relating to the prescribing of specialist drugs in relation to shared care to include clinical responsibility, cost shifting, availability of medicines, GP satisfaction, and the nature of the prescribing relationship. Crowe et al (2009) identified additional factors in relation to prescribing specialist drugs but these were specifically based around the decision making process that GPs needed to go through in managing requests to prescribe specialist drugs. Suggested improvements in the use of shared care protocols have included the need for joint agreement between primary care and secondary care (Salt et al 2005) and having a clearer definition of roles and responsibilities (Gerada and Tighe 1999, Salt et al 2005, Lilife et al 2006).

**Table 3.5 UK studies of shared care protocols**

Authors	Design	Results	Outcomes
Gerada and Tighe (1999)	A national survey of all of the former 120 Health Authorities to provide details of shared care protocols. This was conducted on behalf of the Royal College of General Practice and Psychiatrists Working Party in relation to shared care protocols for drugs used in substance misuse.	Review criteria included patient suitability, guidelines for initial assessment, prescribing, continued care and the extent of GP involvement. From 89 responses received only 26 Health Authorities had shared care arrangements. In only 9 cases was a GP involved in their development.	Few Health Authorities involved GPs in developing shared care protocols even though they were expected to adhere to them. The Working Group concluded that shared care could be achieved if there was close contact between GPs and specialists, integrated training, audit and agreed protocols to include prescribing responsibility.
Duggan et al (2001)	A national survey of hospital pharmacists, pharmaceutical and medical advisers in the former 120 Health Authorities. Qualitative interviews with 8 health care professionals including GPs, prescribing advisers and hospital based clinicians.	A total of 321 shared care protocols were identified that described 99 different specialist drugs and treatments. Shared care protocols were found to vary considerably with no apparent standard either within or between regions; with GPs were commonly excluded from their production.	The authors reported that although a large number of shared care protocols had been produced in the UK, the actual benefits to patients was unclear. There appeared to be no formal evaluation of their use or mechanisms for their implementation and that distribution was found to be erratic.
Horne et al (2001)	To investigate the views and experiences of GPs and hospital doctors about arrangements for shared care in relation to the prescribing of specialist drugs. Semi-structured interviews with London based GPs (n = 48) and hospital doctors (n = 13)	Key themes formed the basis of 8 quality indicators relating to prescribing specialist drugs and shared care to include clinical responsibility, cost shifting, availability of medicines, GP satisfaction; and the nature of prescribing relationship.	GPs appeared dissatisfied with shared care protocols for prescribing specialist drugs whilst hospital doctors appeared satisfied. GPs were more likely to participate in shared care prescribing if they felt hospital doctors were supportive and more understanding of their position.

**Table 3.5 UK studies of shared care protocols (cont.)**

Authors	Design	Results	Outcomes
Salt et al (2005)	An investigation of perceptions of GPs about the prescribing of the specialist drug methylphenidate in the management of Attention Deficiency Hyperactive Disorder (ADHD). Semi structured interviews with 13 London based GPs and a questionnaire survey of 179 GPs based in the same London area from which 93 responses were received.	Whilst GPs had differing views of the aetiology of ADHD, there was a consensus view about the division of responsibility in the treatment of those diagnosed with ADHD. GPs felt uncomfortable initiating the prescribing of methylphenidate and stressed the importance of ongoing specialist involvement in the management of ADHD. There was also a feeling of inadequacy in terms of the training that GPs had received	The authors suggested that once guidance on the initial diagnosis of ADHD was made available to GPs, shared care protocols could be agreed between primary care and secondary care so that the ongoing division of labour in the management of ADHD was made explicit, ensuring continuity of care.
lilife et al (2006)	An investigation of the perceptions of GPs and specialists about the potential for shared care in dementia. Semi-structured interviews with 39 GPs and 30 specialists in 3 inner city and 2 rural areas.	Broad themes were identified as barriers to successful implementation such risk reduction or avoidance; concerns about competency and resources for shared care. Resistance to shared care mostly came from general practice reflecting concerns on staffing, time constraints, lack of experience and confidence in making and disclosing a diagnosis.	The authors suggested that roles for primary and secondary care professionals were inappropriately distributed and required clearer definition. Developers of shared care protocols were advised to address obstacles including risk management and clinical competence.
(Crowe et al 2009).	An investigation of the influences on how GPs evaluated requests to initiate a specialist drug and whether to go on and prescribe. Semi-structured interviews with 47 health professionals in the North West of England including 14 GPs. Other participants included prescribing advisers, GP practice managers and strategic leads representing prescribing committees.	Six diverse factors were identified as having a crucial bearing on how GPs evaluate initial requests and subsequently decide whether or not to prescribe. These included GPs' lack of knowledge and expertise in using specialist drugs, the shared care arrangement, the influence of a locally agreed advisory list, financial and resource considerations, patient convenience and GPs' specific areas of interest.	The authors highlighted a number of recurrent themes with reference to previous studies such as concerns with knowledge and experience of using specialist drugs levels by GPs. The authors identified factors that influenced GPs' acceptance and prescribing of specialist drugs including the importance of an increased understanding of GPs' decision-making process.

### **3.4 Summary**

The use of shared care protocols has been identified as one way of reducing some the risks associated with the prescribing of specialist drugs by GPs including the on-going management of patients. However the outcomes from published studies that have investigated the use of shared care protocols has shown a number of drawbacks in their use. Four of the six studies that have investigated the use of share care protocols in the UK used qualitative methods by way of semi-structured interviews with a range of health care professionals (Horne et al 2001, Salt et al 2005, Iliffe et al 2006, Crowe et al 2009). Duggan et al (2001) adopted a mixed method approach combining interviews with healthcare professionals with a national survey. Although using information technology has been suggested as a possible solution to some of the problems associated with the primary care and secondary care interface (Hampson et al 1996) and more recently with increased expectations following the introduction of the single electronic health record and the greater electronic transfer of information (Khambh and Barnick 2007) to date no published studies have evaluated the potential for a CDSS to support prescribing in this area.

### **3.5 Aims and objectives**

The aim of this study is to assess the feasibility of developing a CDSS to support GPs at the point of prescribing in the use and management of specialist drugs. The objectives for this study were the following:

- Gain an understanding of current usage, system types and characteristics of CDSS within primary care.
- Build a practical understanding of current NHS management systems in relation to information technology, general practice and CDSS
- Explore how current financial constraints with the NHS may impact the delivery of CDSS in primary care
- Understand from commercial suppliers both historic, current and future strategy with regards to CDSS particularly in light of current NHS reforms
- Explore with secondary care clinicians the shared care protocol development process and the feasibility for incorporation into a CDSS for general practice

### **3.6 Methods**

Oppenheim (1992) described exploratory interviews as the basis of initial research that can go on to develop large scale standardised data collection in the form of surveys. In addition Oppenheim (1992) described exploratory interviews as heuristic, as a way of developing ideas and research hypotheses rather than to obtain statistics or facts and that the role of the interviewer is not data collection but idea collection. Spradley (1979) identifies three key requirements for interviews as having explicit purpose, ethnographic explanation and ethnographic question. Explicit purpose requires recognition between the researcher and the informant that the interview as an aim and that the discussions are intended to meet this aim. Ethnographic explanations require the researcher to ensure that the informant is fully aware of every aspect throughout the interview process. Ethnographic questions describe the nature of the question being asked by the researcher and can be descriptive, structural or contrasting.

Britten et al (1995) described the continuing shift in the focus of primary care research through a response to changes in socio-demographic and health environment leading to an increased dependence on a variety of research methods of which qualitative methods as central. Conducting research within healthcare settings has been described as difficult due to a range of factors such as having to deal with people, measuring outcomes, time constraints, ethical issues and dealing with a range of disciplines or professions (Crombie and Davies 1996). However with many of the answers to research questions in healthcare often only available from individuals either patients or clinicians, this lends to the use of qualitative methods such as direct observation, interviews and focus groups. The reality of health services research, including examples of prescribing research is that evidence is rarely complete and a systematic approach to gathering consensus including expert opinion is often required (Campbell et al 2001).

In this study key informant interviews were the best method in order to meet the aims and objectives of the research study. Traditionally established within anthropology and sociology research key informants have increasingly been used within medical research often to complement other qualitative approaches with the principle advantage of obtaining the quality of data in a relatively short time period. A key informant is an expert source of information and usually but not invariably occupies a position of responsibility and influence (Marshall 1996).



### **3.6.1 Selection criteria for the key informants**

A review of the published literature of CDDS usage in the UK identified the stakeholder groups who would provide insight into the requirements of a CDSS to support the use of specialist drugs within general practice. These key informants represented general practice (GPs), NHS management, general practice, secondary care clinicians, commercial CDSS suppliers and industry experts. Sixteen individuals were identified as potential key informants. With kidney transplants accounting for 67% of all organ transplantations carried out in the UK (NHS Blood and Transfusion 2013) renal units were selected as the best suited sites to identify potential contacts. Secondary care clinicians with a specific knowledge of specialist drugs and immunosuppression were based in tertiary care centres providing transplant services. Two GPs known to the primary researcher to have specific interests in the research area were approached. Local NHS IT managers and commercial CDSS suppliers across the UK were also approached.

### **3.6.2 Interview schedules**

The interview schedules were used as a topic guide and emerging themes were used to formulate further questions during each interview. Hancock et al (2009) explained that topic guides should not just be a schedule of questions and should not restrict an interview, which needs to be conducted sensitively and flexibly to allow follow up of points of interest to either interviewer or interviewee. Interview schedules incorporating a range of open and semi-structured questions were developed for each of the four stakeholder groups (see Appendix 3.1, 3.2, 3.3 and 3.4). The schedules were tailored to each stakeholder group with specific questions reflecting the aims and objectives of the study.

- Each schedule included an opening statement that outlined the purpose of the study, confirming consent to participate and for the interview to be audio recorded.
- Each informant was asked about their background, past and current role in relation to the research study.
- Both the GPs and secondary care clinicians were asked specific questions in relation to the views and experiences specialist drugs, immunosuppression and shared care protocols.
- All of the informants were asked about their views and experiences of IT and the feasibility of a CDSS to support the prescribing of specialist drugs.

### **3.6.3 Audio recording**

A Sony digital audio recorder (ICD PX312) was used to record the interviews. Each interview schedule had an introductory statement to remind the informants that the interview was being audio recorded.

### **3.6.4 Ethical approval**

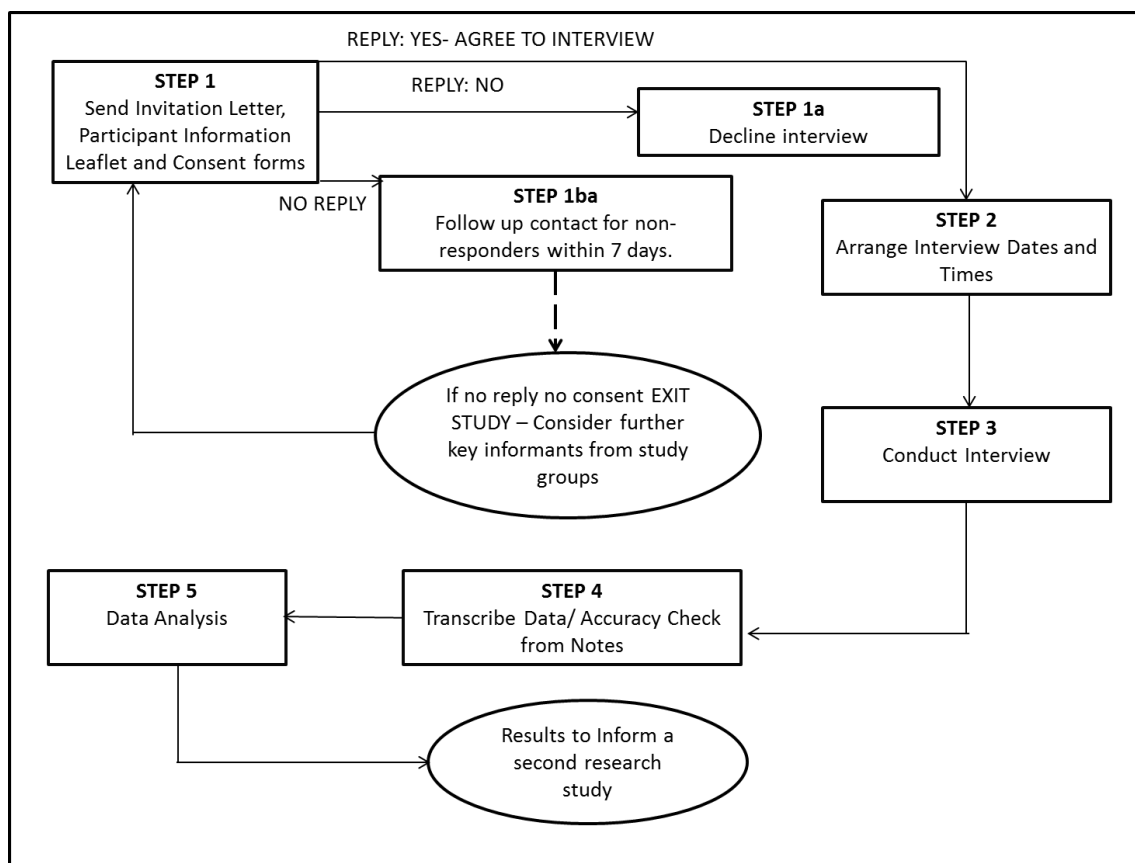
Ethical approval for the study was granted by Kings College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee on the 28th May 2012 (Reference BDM/11/12-82).

### **3.6.5 GP pilot**

The GP interview schedule was piloted prior to the first interview. A GP known to the researcher was approached and agreed to participate. The interview lasted 20 minutes and was transcribed verbatim into Microsoft Word (Version 10). Following a review of the transcript no changes were required to the GP interview schedule.

### **3.6.6 The interviews**

The flow diagram (see figure 3.4) summarises the methods used in this study. Each potential key informant was first sent a cover letter (Appendix 3.5), participant information leaflet (Appendix 3.6) and a consent form (Appendix 3.7) either electronically and or by post. Any non-responders and any participants declining consent were exited from the study and further informants were considered. Participants who agreed to take part were then sent a confirmation letter (Appendix 3.8) and contacted to arrange a suitable time and venue. All interviews were arranged at locations convenient to each participant e.g. office. Additional notes were taken during each interview which included observational data such as work-place environment.



**Figure 3.4 Summary of methods followed during this research study**

### 3.6.7 Interview transcripts

Following each interview the recordings were transcribed verbatim onto Microsoft Word (version 2010) and each document was checked for accuracy saved as a final transcript with an individual anonymous participant code. The software NVIVO (version 10) was used to support data analysis.

### 3.6.8 Data analysis

Qualitative research uses analytical categories to describe social phenomenon, derived either inductively, i.e. gradually from the data obtained or deductively either at the beginning or part way through data analysis (Pope et al 2000). A review of the literature had identified specific themes which pre-determined the analytical categories such as the experiences of individuals of CDSS, specialist drugs and shared care protocols. Specific techniques that have been developed to support the analysis of data generated from qualitative research to include grounded theory and framework analysis (Lacey and Luff 2009). Framework analysis is an inductive process of identifying analytical categories developed in the 1990s by UK by social policy researchers (Ritchie and Spencer 1994).

Although the approach to framework analysis shares many features of grounded theory, this approach allows categories and themes to be set at the beginning of analysis, but also allows for the generation of new ideas during data analysis. Framework analysis was chosen as the method that best supported data analysis and would allow for identification of additional theory or the generation of new ideas or concepts.

As each interview was conducted and transcribed, initial analysis was conducted manually through a process of iteration of the text to allow the researcher (NC) to identify emerging themes and sub-themes. These emerging themes were then categorised both manually and using the software NVIVO (version 10). These themes were used to further develop each interview guide in order to explore key areas and amend existing or to add further questions for the subsequent interviews. Emerging themes and sub-themes were categorised and charted to identify patterns, relationships, contrary statements and conflicting issues. Themes and categories were continuously reviewed and re-coded as new data emerged from each interview.

### **3.6.9 Data quality analysis**

On completion all 12 interviews were re-checked for accuracy. NVIVO trainers (BW, TM) were consulted to check coding methodology and data mapping. In order to provide more accurate reports and enhanced analysis. A second round of coding was completed, and validated with the trainers. A number of iterations of the data set were completed and agreed with the research team (NC, CW, BD).

## **3.7 Results**

Twelve interviews were completed between July 2012 and February 2013. The interviews lasted between 30 minutes (GP1) and 65 minutes (DS3) with a mean interview time of 50 (49.75) minutes. A summary of the interview schedules and key informant background profiles are shown in Table 3.6

**Table 3.6 Profile summary of the 12 key informants**

Month	Stakeholder Group	Informant Code	Interview Duration	Profile Summary
July 2012	GP	GP1	30 minutes	Recently qualified and worked as a salaried GP based within a large health centre
August 2012	NHS IT Manager	IT1	49 minutes	Recently appointed to the NHS and was working across 3 PCTs on a GP practice refresher project.
August 2012	CDSS Industry	DS1	55 minutes	Pharmaceutical consultant specialising in health informatics.
August 2012	GP	GP2	49 minutes	Qualified for over 8 years and a partner within a five doctor practice.
September 2012	CDSS Industry	DS2	62 minutes	CDSS supplier representative.
September 2012	NHS IT Manager	IT2	43 minutes	GP practice manager with over 20 year experience in NHS IT roles including senior management
September 2012	Secondary care clinician	NHS1	49 minutes	Lead pharmacist on behalf of a specialist commissioning group
October 2012	CDSS Industry	DS3	64 minutes	CDSS supplier representative and qualified GP
December 2012	Secondary care clinician	NHS2	50 minutes	Lead directorate pharmacist NHS renal unit
December 2012	Secondary care clinician	NHS3	47 minutes	Consultant in renal medicine
February 2013	CDSS Industry	DS4	61 minutes	CDSS supplier representative and a qualified GP
February 2013	Secondary care clinician	NHS4	38 minutes	Consultant in renal medicine

The research area specifically focussed on primary care and GP prescribing however a number of features of secondary care based systems and clinical practice emerged in relation to the research area. Three primary themes were identified from the data from which a range of secondary themes and sub-themes emerged and these are shown in Table 3.7.

**Table 3.7 Summary of primary, secondary and sub-themes**

Primary Theme	Secondary Theme	Sub-Themes
Safety	Prescribing, monitoring, specialist drugs, shared care protocols, commissioning of services (secondary care)	<ul style="list-style-type: none"> <li>• Communication: Problems specifically between primary care and secondary care (interface)</li> <li>• Clinical responsibility: For GPs when prescribing specialist drugs</li> <li>• Monitoring of patients receiving specialist drugs</li> <li>• Experiences of specialist drugs (adverse experiences such as drug interactions, generic prescribing, repatriation)</li> <li>• Experiences of shared care protocols</li> </ul>
IT Systems	Operational features of IT systems (primary care)	<p>General usage of computers in general practice and key characteristics of IT systems</p> <ul style="list-style-type: none"> <li>• Regulation (current NHS management systems, GP system vendors and shifting to hosted systems)</li> <li>• Data quality (read coding, accuracy, accreditation)</li> <li>• Integration of systems</li> <li>• Implementation of systems</li> <li>• CDSS and experience in general practice (current profiles, usage and characteristics)</li> <li>• Current and future developments in CDSS</li> <li>• CDSS and specialist drugs (views and attitudes , enablers, barriers)</li> </ul>
Cost	Drug costs, service costs, IT funding (general practice), CDSS funding models	<ul style="list-style-type: none"> <li>• Prescribing budgets (primary care)</li> <li>• NHS service costs and use of homecare</li> <li>• GPSOC (License fees), CDSS funding streams</li> <li>• CDSS and specialist drugs: Funding models (barriers and enablers)</li> </ul>

### **3.8 Primary themes**

Three primary themes emerged from the data analysis and a number of sub-themes. The primary themes were safety, IT systems and costs.

#### **3.8.1 Safety**

Aspects of safety were raised throughout the interviews particularly from specific experiences of using specialist drugs in terms of prescribing and in the on-going management of patients receiving immunosuppressant drugs. The experiences of the informants described key concerns, difficulties and having to deal with adverse situations or outcomes.

##### **3.8.1.1 Communication**

Issues with communication between primary care and secondary care were described by the GPs and secondary care clinicians. A lack of documentation coming from secondary care was a specific issue for the GPs and for the secondary care clinicians. Problems with communication were described in terms of differences in medication records between primary and secondary care (see Box 1).

#### **Box 1: GPs and secondary care clinicians' experiences of communication**

GP1: "Relatively frequently, if I see a prescription for mycophenolate and tacrolimus on the whole, I think they are the only ones I have prescribed, I look to try and repatriate the prescribing to secondary care, because frequently we have minimal documentation."

NHS2: "We start blood pressure tablets.....we stop blood pressure tablets....we change blood pressure tablets.....we withhold drugs because of side effects....we communicate this to GPs....but the patient.....X months later are still on the same drugs."

NHS4: "Well I would say that the actual transcription errors are relatively rare in relation to the drugs, but not unknown.....more often just simply it's what I think they are taking is completely different to what the GP thinks they are taking."

### **3.8.1.2 Clinical responsibility**

Clinical responsibility was described from a range of experiences by the informants highlighting a number of concerns (see Box 2). The issue of clinical responsibility and its effect on the willingness to prescribe was described by both the GPs and secondary care clinicians. One initiative described was the use of traffic light schemes whereby certain drugs would remain hospital only based on their classification but could be prescribed under certain circumstances by GPs. However even under such conditions one secondary care clinician empathised with the difficult position that a GP may face when asked to prescribe specialist drugs that they were not familiar with.

#### **Box 2: GPs and secondary care clinicians' experiences of clinical responsibility**

GP1: "I think you know about where the responsibility lies, at what stage in therapy the patient is, because often the letters come weeks after the clinic, that's no good, they come to us 2 weeks later, we don't know what their dose is, we don't know if have they completed a dose escalation, you know.....we are.....basically operating in the dark, but we are being asked to prescribe these drugs."

GP2: "Anxious.....you are often being asked to take responsibility for something that actually we don't have the authority or the control over where the consultant in a hospital would."

NHS3: "I didn't feel particularly strongly that they either should or shouldn't be prescribing I can see their point, they are not drugs they are used to....if you make me prescribe some drug for hepatitis which is something out of my expertise I would be uncomfortable about it as well."

### **3.8.1.3 Monitoring**

The overall clinical management of patients was described by both the GPs and the secondary care clinicians. This management included specific aspects about patient monitoring and are described in Box 3. The GPs described experiences where patient monitoring around blood test results posed practical difficulties. In contrast to the GPs, the secondary care clinicians described positive aspects to the clinical monitoring of patients receiving immunosuppressant drugs. In addition clinical monitoring was described as a key aspect of hospital based reviews.



**Box 3: GPs and secondary care clinicians' experiences of the monitoring of specialist drugs**

GP1: "Similarly we might get a blood result, that's potentially very worrying for somebody on mycophenolate, but not worrying at all for somebody with slightly low neutrophils, you wouldn't panic.....somebody who is not taking mycophenolate you would just call them in.....but if that was somebody taking mycophenolate they need to have a blood test and hospital admission immediately."

GP2: "Only 2 days ago I had a patient who wanted their medication but no blood test been done for 6 months, I tried to ring them.....no answer.....so what do you do in that scenario?"

NHS2: "For the frequency that you would need to monitor levels once they are stable they only need to be done whenever they come up to clinic so there is no point for the GPs doing their bloods anyway so as long as they keep an eye on their blood pressure."

NHS4: "It's got a lot more complicated in the modern world.....in the old world when all there was branded ciclosporin it was straight forward, as a general rule in those areas where local primary care had agreed to do the prescribing it was generally expected that the renal unit would be in charge of the level and the GPs would adjust the dose as requested by the renal unit."

**3.8.1.4 Experiences of specialist drugs**

A key aspect to medication safety were citations and examples of adverse effects linked to the prescribing of immunosuppressant drugs by GPs and the secondary care clinicians. These related to two key areas drug interactions and the introduction of generic formulations of tacrolimus.

**3.8.1.4.1 Drug interactions**

Shown in Box 4 were specific adverse experiences with drug interactions with immunosuppressant drugs. One practical difficulty in relation to drug interactions faced by GPs was that when hospitals prescribed specialist drugs that information was not able to be made available electronically within the patient medication record held within the GP clinical system. Without such drugs recorded on a GP held medication record there is a potential for other prescribed drugs to interact.

The secondary care clinicians described adverse experiences of drug interactions including examples when patients were given drugs prescribed by their GPs whilst taking immunosuppressant drugs.

**Box 4: GPs and secondary care clinicians' experiences of drug interactions with specialist drugs**

GP1: "One of the practical difficulties for us is that often it's not logged on our computer system, that if they are receiving the drugs from somewhere else.... the HIV drugs, the TB drugs, mycophenolate, tacrolimus, they might be prescribed by specialist clinics, we get clinic letters that tell us, but it does not automatically appear on our prescribing system, so potentially drugs that we prescribe might interact with that, unless we have put some sort of alert on the system."

NHS3: "I think drug interactions is one of the major headaches that we have with immunosuppressants, you know mainly penicillin allergic patients come in with a fever and a chest infection and they get clarithromycin and then the next thing you know their tacrolimus levels have doubled."

**3.8.1.4.2 Generic prescribing**

The patent expiry of ciclosporin, mycophenolate and tacrolimus has allowed the introduction of generic formulations of these drugs. However the secondary care clinicians described a number of adverse events involving generic formulations, particularly with tacrolimus, due to differing bioequivalence between these products. Examples of inadvertent switching of formulations are shown in Box 5.

**Box 5: Secondary care clinicians and experiences of generic prescribing of immunosuppressant drugs.**

NHS1: "When the primary care data was analysed it appeared that patients had been getting different formulations.....well inappropriately.....so basically no decision had been made to change it but it had been changed so there was a patient safety imperative around bringing patients back."

NHS2: "So that's the other thing they did we said specifically you have to give Prograf and the GP was going oh well that's too expensive and I will give you Vivadex instead.....well they killed the patient."

NHS3: "There is a huge variation in bioequivalence, we had one patient who had the wrong brand of tacrolimus and came in and rejected due to lower levels of tacrolimus.....we had another patient who came in who had a recurrence of herpes zoster because she had received a different brand and had been over immunosuppressed."

#### **3.8.1.4.3 Repatriation**

The introduction of generic immunosuppressant drugs and the associated number of number of adverse incidents was a key factor that led to the decision to revert GP prescribing back to renal units across the country. The secondary care clinicians described this process as repatriation with the added benefit of making use of homecare services to provide patients with their supply of immunosuppressant drugs (see Box 6). A specific service development was the introduction of pharmacist prescribing within one of the renal units.

#### **Box 6: Secondary care clinicians and experiences of repatriation and use of homecare Services.**

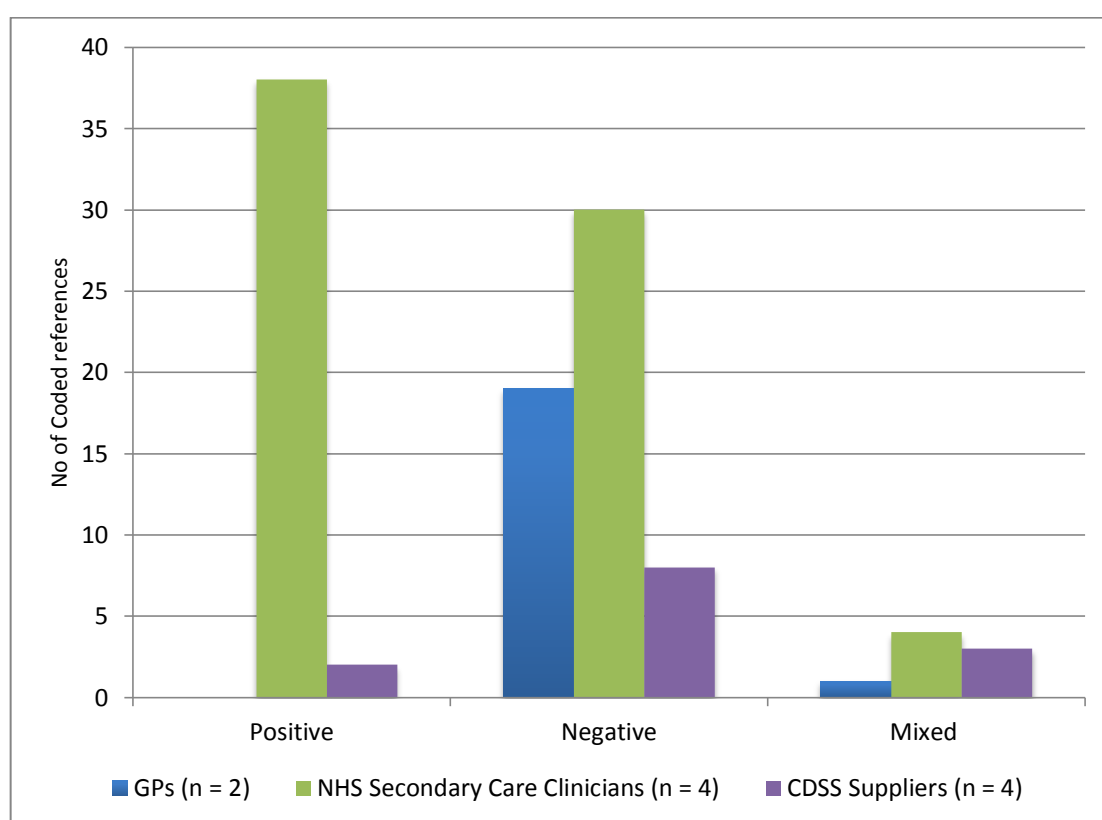
NHS1: "There are cost advantages to using the generic products, but there are big issues about when you need to stabilise the patient, if you're going to do this then patients need further work up to enable it this to happen and then you have to be consistent afterwards with the choice of products, so the process has been that patients have been if you like.....migrated back to the specialist centres, had these changes made and then continued to be under the care of the specialist centre with the medicines reaching them through homecare."

NHS2: "Three of us are prescribing pharmacists so we spend a morning a week each in the transplant clinic doing all the prescribing for them.....the prescriptions are on a proforma we have developed.....what we do then is that we take them downstairs and the bods in the offices scan them, encrypt them and they can then send them via NHS mail to the homecare companies."

NHS4: "As I said earlier on all my life as a consultant, worked in units where the prescribing was central, whether it was home delivery or not.....so the home delivery or not issue to me is seeing that it is convenient for the patient, and the VAT gain for the ultimate payers and that is good as well.....I think repatriation is a good thing.....with transplant immunosuppression that is the rational way to do it."

### 3.8.1.5 Shared care protocols

The informants described mixed experiences of shared care protocols and highlighted some of key concerns in relation to safety such as communication between secondary and primary care. The views and experiences of the GPs in relation to shared care protocols were particularly negative. The secondary care clinicians reported a greater experience of shared care protocols describing some positive aspects to their use such as the developmental and approval process. Two of the CDSS informants were practicing GPs and shared their experiences and opinions in this area. Figure 3.5 shows the views and experiences of the informants of shared care protocols by stakeholder group.



**Figure 3.5 The views and experiences of the informants of shared care protocols by stakeholder group.**

#### 3.8.1.5.1 Development and approval of shared care protocols

The secondary care clinicians provided specific insight on the developmental process of shared care protocols and these are shown in Box 7. These included writing, updating and the approval process including the relationship with primary care based medicines management teams.

Positive aspects related to the developmental process however some drawbacks were described in relation to the approval process and engagement with primary care. Although GPs were involved at the approval level neither of the GP informants had any experience in the writing of or development of shared care protocols.

**Box 7: Secondary care clinicians and the developmental process of shared care protocols**

NHS 1: Generally they take a good deal of effort to create.....the challenges again around....you often work with a partner, say a primary care partner to develop the thing, so it meets everybody's needs, so you think you can then lift that model and apply it to the next commission group or PCT.....to make these things happen and often there is a two part process so there may be a pharmacist in the Trust leading on it and working with a particular head of medicines management or a PCT colleague and that is usually ratified through processes of the PCT and the drug and therapeutics committee of the hospital."

NHS2: "I have written quite a lot of them.....usually renal drugs.....once I have written it I send it to our formulary pharmacist.....and then she goes to meetings with the local PCTs.....rather than the individual PCTs now we deal with the Sector, so it's all the old PCTs in sort of one lump, she goes to meetings with them and that's where these things get thrashed out and they come back for comments."

NHS3: "We have always had a shared care protocol for immunosuppressants, we updated it with the idea that generics were coming along, we updated it with the idea that Advagraf was coming along too"

NHS4: "Historically it has tended to be slightly one sided from the secondary care end.....the secondary and tertiary sector is where the experience and expertise is...so that's not totally unreasonable.....and it will depend on the certain extent on the energy, knowledge and desire from the representatives from primary care who are involved."

**3.8.1.5.2 Quality of shared care protocols**

Despite the positive description in terms of developing shared care protocols and the approval process involving PCT medicines management teams the opinions and experience of the GPs raised doubts on whether these systems were effective with the most widely cited problem being the quality of shared care protocols.

A number of examples were given describing specific issues such as inappropriate drug selection, variability, and the ease of use in general practice. The views of the GPs on the quality of shared care protocols are shown in Box 8.

**Box 8: GPs' views on the quality of shared care protocols**

GP1: "I never had any awareness of shared care protocols, I think they are universally pretty useless and I think they are a significant area of potential danger."

GP1: "I understand there are some shared care protocols which exist which I think are routinely flouted and are probably quite silly, for example around acetyl - cholinesterase inhibitors.....yet we are being asked to prescribe things like mycophenolate and ciclosporin which I don't think are benign at all and have significant risks and I don't think are appropriate for primary care, and It just seems to me there is no sense to it."

GP2: "My normal first response is no we won't take this on until we get the protocol and when it is sent it is not written in my perspective.....in the sense that it's often written from how it's initiated.....not terribly helpful or easy to use."

**3.8.1.5.3 Acceptance of Shared care protocols**

The secondary care clinicians described the acceptance of GPs to prescribe specialist drugs by way of a shared care protocol as particularly problematic (see Box 9). Despite having shared care protocols available often supported by local NHS medicines management teams or similar authoritative processes, did not specifically mean that GPs would use them.

**Box 9: Secondary care clinicians and experiences of the acceptance of shared care protocols by GPs**

NHS 2: "Well the shared care protocols were out there whether they used them or not.....I have no idea.....the bosses of the PCTs kept saying oh we have to update it.....whether that was to make them feel good, or who actually used them I have no idea

NHS2: "About 50 / 50 (of GPs).....but it was getting worse.....and even some who did prescribe turned around and said no I won't prescribe."

**Box 9: secondary care clinicians and experiences of the acceptance of shared care protocols by GPs cont.**

NHS3: "Yes, the request had come from the GP.....then you can send out the shared care protocol, I have not had an awful lot of feedback from primary care about the shared care protocol.....sometimes I have had a number of multiple requests from a similar GP.....It's like everything .....a piece of paper that you get in the post.....oh gosh that's fantastically interesting, I must remember that the next time I see a patient with that.....but it gets filed.....and then the patient comes along and you have to trigger it in your memory that you have that shared care protocol."

NHS3: "So there were multiple different reasons.....one was the traffic light system.....so it would be either red or amber....so they would say that my local PCT has said this is red or amber and therefore I shouldn't be prescribing."

**3.8.1.5.4 Availability of shared care protocols**

Ensuring the availability of shared care protocols and the awareness of their existence was a key problem and this is described in Box 10. The GPs identified the absence of shared care protocols when receiving communications from hospitals and also identified that often secondary care clinicians were not aware that a protocol existed. The secondary care clinicians also described issues with the availability of shared care protocols. Difficulties included keeping track of and locating updated versions and ensuring dissemination to all GPs to include locums.

**Box 10: GPs and secondary care clinicians' views on the availability of shared care protocols.**

GP1: "I think it's something that we frequently get letters from the hospital consultants.....you know or this is the drug they are taking, it's not made clear to us if we're expected to take on prescribing, it's not made clear to us if there is a shared care protocol in place, it's certainly not clear that they have any idea if there are shared care protocols in place."

GP1: "I am sure they are available on this formulary, somewhere.....but the reality is this that this data isn't very accessible to the average GP..... there are so many of them that we are just overwhelmed with it, I think most GPs.....I certainly shy away from prescribing things like tacrolimus."

**Box 10: GPs and secondary care clinicians' views on the availability of shared care protocols cont.**

NHS1: "Yes in the sense that I hear that argument, and you know it's very real if the information is not available.....wherever it's getting it embedded in the system..... obviously it's whether it is there but not findable."

NHS 4: "I think that we do sometimes get sort of howls of protest if we try to set up something too complicated....."Listen we are drowning in paperwork!"..... Protocols are forms.....things get updated, you have to keep track of the version, you have to have them easily available, every time a new one comes out you have to update everything, you have it set up so locums and other people coming in to the environment knows where to find them.....it's big pain in the neck!"

**3.9 Information technology: Systems and functionality**

IT systems within the NHS were described from both historical and current perspectives in both primary and secondary care settings. The majority of experience as expected was in primary care and general practice. All of the informants were able to relate to their experiences of IT systems with emerging themes highlighting key aspects not just in relation to operational functions and features but key relationships between system suppliers, end users and NHS IT management.

**3.9.1 Computer use in general practice**

The use of computer and IT systems were described from end users perspectives (GPs and practice staff) and from a management perspective in terms of the technical support that was required (see Box 11). A range of operational issues emerged that highlighted a mixture of experiences around computer usage, however it was overwhelmingly clear that computer systems were central to the management of GP practices and were being used for a wide range of both clinical and non-clinical activities. Features from a non-clinical perspective highlighted the increasing workload of general practice over time and hence the importance placed on computer systems to manage the practice on a day to day basis. Overall, a mixed picture was portrayed of computerised systems and acceptance of new technologies. Positive benefits were expressed particularly from a clinical aspect such as prescribing support and supporting the running of GP practices. Some of the problems cited described technical issues with GP practice IT systems and the level of aptitude of end users including GPs.



**Box 11: Informants' experiences of computer use in general practice**

GP1: "I think our computer system is central to pretty much everything we do, all of our records are electronic so past medical history is electronic, all our pathology and radiology results are sent to us electronically, and all of our letters are scanned on to our computer system."

GP2: "All of our records, our prescriptions are electronic, anything that comes into the practice that isn't electronic.....you know letters will be scanned.....our business is almost entirely reliant on it."

IT1: "Yes, we cover right the way through from the PC itself, the server.....and applications so the day to day tools such as office products.....and a lot of admin work that goes on, which we were quite taken back at how much work is actually happening in a GP practice"

IT2: "It depends on how IT literate they are to start with, obviously there are the ones that can do everything from consulting to all the way through to all the comprehensive searches, right down to the ones that struggle to even put a consultation on.....they are getting better, it was the older GPs that seemed to have more hassle than younger GPs."

**3.9.2 Key characteristics of IT systems**

The informants described key characteristics of IT systems primarily from a primary care perspective and general practice. The informants described how IT systems were both regulated and managed from both supplier and NHS management perspective. In the UK all IT systems including CDSS are provided by commercial organisations, there is no NHS provider as such. The experiences of the informants portrayed a heavily monitored and regulated framework around primary care and general practice IT systems with overall responsibility resting with NHS Connecting for Health and local NHS commissioning organisations.

**3.9.2.1 Regulation**

NHS regulatory systems for general practice were described by the informants and are shown in Box 12. Key aspects to regulation included the level of conformity of GP clinical systems in relation to core contractual standards with NHS Connecting for Health. The high level of conformity was described not just for current GP clinical systems but in terms of any additional extensions or enhancements.

The NHS IT managers described their roles in terms of providing technical support to GP practices. The CDSS informants described operational aspects to software systems including aspects of conformance with regulatory standards set by NHS Connecting for Health.

**Box 12: NHS IT managers and DS3 experiences of NHS IT regulation**

IT1: "All of the clinical application providers, they have to adhere to Connecting for Health (CFH) standards, so CFH are in that loop when it comes to any kind of procurement.....CFH are involved, the PCT is involved.....these are all external companies, they are not owned in any way shape or form by the NHS, they are completely independent; they have to go through a number of criteria to make sure they can supply their products to NHS bodies."

IT2: "What used to be Connecting for Health used to regulate all the clinical systems and it would all go through beta testing and so would any bolt on applications, and any further enhancements to the clinical systems have to go through clinical testing and be signed off by Connecting for Health."

DS3: "Well sort of test packs and conformance testing of our software and every change we make to it has to be re-conformed to ensure that we are sending the right message at the right time for the right patient and that the message that we send is conforming.....it can be consumed at the other end.....these are computer to computer messages.....they are not designed for humans to read they are designed for the computer system to interact with another computer system.....so they are in compacts.....HL7 messaging standard format in XML.....computer talk."

DS3: "Yes that travels through the spine.....and so do all the EPS messages, the prescription messages, GP to GP record transfer and all the rest of it.....that's highly conformed and tested."

The financial constraints with the NHS and current reforms were also explored particularly with the impact on NHS Connecting for Health and these are shown in Box 13. Current and historical difficulties were described including prospects for the future in terms of the provision of a regulatory framework for NHS IT systems including those for general practice.

**Box 13: NHS Connecting for Health and future regulation.**

Researcher: "With the current situation with the NHS where do you see Connecting for Health in the next 5 years?"

DS3: "Dead, gone.....DH Informatics will continue.....it will certainly have a reduced role in terms of power compared to Connecting for Health..... we need it for standards.....it's just going through its death rows, trying to wrap itself up in the best possible way.....I think it's proved to be failure, I think it needs to be gone."

DS3: "At the end of the day the programs they have established will continue, those programs are not going to die.....I think those programs will persist it will be the end of Connecting for Health, but there will be a DH Informatics, they won't embark on any new ones for a long time.....It's not a lack of money it's a lack of focus."

DS3: "If you look back at the history of the CFH it primarily was a legal contract negotiating body, it was not anything else, it had no clinical input, didn't know what it was doing.....what it was doing was tying up huge contracts to deliver something that was poorly defined."

**3.9.2.2 Hosted GP clinical systems**

Shown in Box 14 were aspects around a trend to move GP clinical systems from practice site based models with computer terminals connected to a server, to hosted systems with terminals connected to a remote server. Some of the advantages of such a move were described including quicker response times from the system vendor and improved data security.

**Box 14: The shift to hosted GP clinical systems**

IT2: "If the server died on us today we would have to wait for EMIS to come out to us which is why they want to move everyone over to hosted systems..... they are regulated data centres, there are always two data centres so if one gets damaged, blown up, whatever, fire.....they will switch over to other data centre so there is always the backup....there is no backup with the GP surgeries, there is no server, there is no hardware apart from the PCs that the GP surgeries have to look after."

**Box 14: The shift to hosted GP clinical systems (cont.)**

Researcher: “So are hosted systems the way forward and is that happening nationally?”

IT2: “Yes, because they are phasing out servers.....because the life of a server is 4 – 5 years.”

**3.9.2.3 Data quality**

The accuracy of data recorded and or data presented within computerised systems was a key theme from both a prescribing perspective and the management of health records. A specific problem and area of concern was the process of managing paper based information and specifically ensuring relevant data was electronically recorded and coded.

**3.9.2.3.1 Read coding**

The process of read coding was described from a technical perspective highlighting strengths and weakness including how inaccuracies can have a significant effect on end users in both prescribing and general patient management (see Box 15). Problems were described with coding accuracy such as in drug nomenclature and the interpretation of alerts or warnings. In addition difficulties included dealing with hospital communications which required manual uploading and read coding on to patient’s electronic record held at the GP practice.

**Box 15: Informants’ experiences of read coding**

DS2: “A number of drugs prolong the QT interval, by a specific precaution or contraindication, if we strictly look at the hierarchy, bring back other cardiac arrhythmias which are less relevant, and there are two sides to that historically.....when doctors started coding, some of the coding was possibly less concise than it should have been.....we now and particularly in the Snomed solution and moving towards it in our Read Solution we are definitely trying to narrow the terms which get more granular, more precise coding.”

DS2: “We had an end user who complained that the pregnancy alerts were showing for his 80 year old patient because he had never told the system she was no longer pregnant.....if you have an episode that has completely finished in the past and is no longer relevant and I suspect in a lot of cases it is still coming up.”

**Box 15: Informants' experiences of read coding (cont.)**

GP2: "Where feasible, if we had the man power we would read code everything in that letter but in reality we read code as much as we can, so as all the information comes in so hopefully we get onto it as a single record and we essentially try and run the business as paperless as we can but it's fairly impossible with prescriptions being based on paper"

**3.9.2.3.2 Accuracy**

The CDSS informants described key processes around the quality and robustness of data (see Box 16). The quality of CDSS alerts were described in relation to the reliability of data and ensuring specific standards were maintained. These were described in terms of both references used to support CDSS and also the authorising process that was followed. In addition legal aspects around authoring alerts and warnings provided by CDSS and whether a GP system supplies its own or it is provided by a third party were also emphasised.

**Box 16: CDSS informants and views of data accuracy**

DS1: "The drug data is obviously quite complex, there are lots of drugs available and doses.....many suppliers get their drug data from third party data suppliers.....the system supplier instantiates that into the system, the drug data supplier has legal responsibility for the quality of the data which takes a burden off the system supplier, and the system supplier can then go to their customers and say this is the level of decision support we provide around allergies, drug interactions, precautions and dose checking"

DS3: "Yes and certainly we have evidence for all our authored drugs, those tend to come from standard sources so the SPCs for the drugs, the BNF, Martindale etc. so that's where they come from, we don't make them up."

DS4: "So there is a whole range.....the majority of messages are actually authored by the CCGs and the PCT.....so the tool basically enables that process and we do provide guidance and support for people on that and we provide lots of feedback and other data to enable them to get the messages."

Both GPs emphasised the importance of being able to trust alerts (see Box 17). Being able to trust data being presented was a key area for end user of computerised systems for a range of areas to support prescribing including drug information, costs and aspects around safety.

**Box 17: GPs and experiences of data accuracy**

GP1: "I think that's possibly a danger, but.....you know in most of the prescribing I do, it does it in a very conservative way, it still requires you to acknowledge the change, it only makes the change temporarily, and I mean, I suppose there is a risk with it, but I think in simple things like Script-Switch it's fairly negligible, it's not like a change of category of drug, you're just changing formulation, and the dosing conversion is fairly accurate."

GP2: "Personally I like it (Scriptswitch), it's entirely reliant on the quality of the database behind it.....I know if it's up to date, contemporary and being updated I will pay attention to it, once I read a message twice or If I start reading a message which is out of date, then I start losing faith in the entire product."

**3.9.2.3.3 Accreditation**

A key aspect in relation to data quality was the accreditation of CDSS which was described from a range of perspectives by the CDSS informants (see Box 18). Although GP computer system suppliers are required to meet strict regulatory and conformity standards set by NHS Connecting for Health, such levels of quality management for CDSS were described as lacking. One of the informants reported that a specific CDSS was ISO accredited, and described an application for accreditation with NICE. In addition the informants described recent European legislation that classified stand-alone software including CDSS used in healthcare within the regulatory framework of medical devices. The informants described concerns with aspects of this legislation such as interpretation, implementation and financial penalties for non-compliance.

**Box 18: CDSS informants and views of accreditation**

DS1: "Well that's a very good question, and the situation at the moment is that there are no specific guidelines.....now there are organisations like Intellect, which is like a sort of trade body for the system suppliers, and they certainly help with a lot of issues around implementation of new requirements, but in terms of actually what decision support is required there are no specific regulatory requirements."

DS2: "We are a fully ISO accredited company, so we are audited by an external auditor annually and all the work on the database is fully underpinned by editorial policies and work instructions which are regularly reviewed.....we are the only clinical decision support system that has got NICE accreditation at the moment."

DS3: "The MHRA are lost completely in the medical devices directive with the proposition from Europe that software can be a device, and they don't know how to do this.....we are going through the process of registering our decision support elements of the software as a device under that Directive yes, because we believe that that's what we are being told we must do, I think it will make no difference to anything other than avoid us being fined for not doing it.....so we would have to declare it.....and if we don't declare it we are likely.....it is possible.....there is the potential for us to get fined under European Law for not declaring it.....but no one is going to test it.....the testing is ours."

DS4: "Yes there are laws.....there is very heavy regulation.....and there are fairly heavy fines, potentially imprisonment and I don't think there has been anyone who has developed anything that does not comply as the penalties are too high."

**3.9.2.4 Integration of systems**

The NHS IT managers described examples where problems with integration of systems caused difficulties for GP clinical system suppliers (see Box 19). Integration was described as key to both improving current systems and the way future CDSS could be developed.

**Box 19: NHS IT managers and experiences of software application integration**

IT1: With all of these clinical applications they will only provide functionality for what they are in business for, so if they are looking at the prescribing side of things that's all they will be interested in, so If you want to integrate something else in then both parties need to look at the software application and integrate it in such a way so that it is completely seamless, and it works transparently and the way it should work.....at the moment a lot of these third parties are going out and developing products and tools that do not integrate and that's where a lot of these are failing."

IT2: "Knowing the clinical systems to start with and knowing how to integrate with them.....if it was part of the same system that would not be a problem so (integration).....it's the key thing.....you don't want to be doing all that.....and then you go back to EMIS again.....it all has to be integrated into one clinical system."

**3.9.2.5 Implementation of systems**

The informants described mixed experiences of how either new systems or enhancements of current systems were implemented both from an IT management perspective and from end users. The NHS IT managers described specific experiences where the implementation of systems and projects were problematic (see Box 20). Key issues raised included a lack of planning, training and engagement with end users and were described in relation to a range of systems and applications.

**Box 20: NHS IT managers and experiences of IT project implementation**

IT1: "Looking at the work we have done in the last 2 - 3 years I think it has been the most challenging for us as department to deal with.....we have to roll out new hardware, a lot of these GPs are using machines that are no longer supported by Microsoft, no longer supported by clinical service providers, so they have to be upgraded.....when you roll out new kit it just comes with the new applications and you can't run the old applications on new devices."

IT2: "Time constraints.....a lack of training.....that is the norm.....they will implement something but they will not be a full training package in place.....health numerics for example they did the training for health numerics months ago.....they have got a drop in session available but they told us about that on Thursday, so people have got things booked and you can't go, but there doesn't seem to be another training session, there was a training session today and that was it."



### **3.9.2.5.1 Implementation of IT systems and the needs of end users**

The relationship between end users of GP clinical systems and suppliers was described from a range of perspectives by the informants. These experiences were mixed and highlighted issues arising from system use and in on-going development of products. Some of these experiences were in relation to new or existing IT roll out and implementation. A key aspect was engagement with end users of GP clinical systems through end user groups. Box 21 shows the experiences of the CDSS informants with end users. The informants described a range of mixed experiences and perspectives between the IT industry and end users. It was acknowledged that over alerting was a problem with CDSS and that was from feedback from GPs through user groups and also described how end users were involved with product development. The interaction between GP system vendors and user groups in particular detail was described as complex with problems arising between users of the clinical system, both GPs and practice staff.

#### **Box 21: CDSS informants and experiences with end users**

DS2: "All of our system vendors have their own support desks, so certainly they field particularly technical queries from the end users if they tend to be clinical queries on the database they come through to us, we also attend some of their user groups and certainly some of the system vendors have what they class as super users so they can try their new developments on a small group before rolling them out to much wider users."

DS3: "We have user groups we interact with frequently, we have national user groups.....there are on-line forums.....we take lots of feedback from our users of our products.....be careful about the fact that anybody thinks they can influence a product....so we have got have 2,500 practices, 10,000 GPs, 30,000 receptionists who all think they have the answer to how you should change it for everybody."

DS3: "So they both have phenoxymethylpenicillin 250mg tablets.....but one says 250mg tablets but the other says tablets 250mg.....trivial you might think, but it's not, because it is change.....end users do not like change.....what was working OK has been changed and that can be disruptive and they don't like it.....so user impact is the probably the thing what you should take most into consideration."

### **3.10 CDSS in primary care**

In total 25 CDSS were referred to as either in use in general practice or respondents were aware of as being used or available to GPs, of which 9 were active CDSS and 16 passive and these are shown in Table 3.8. Each of the five current GP clinical system providers provided in built active CDSS to support performance in relation to the current Quality and Outwork Frameworks (QOF) component of the national General Medical Services (GMS) contract in the form of reminders and prompts. Integration allows data capture to a national database known as QMAS (Quality Management Analysis System) which gives GP practices and PCTs reports on achievement against QOF indicators and calculates QOF payments Drug databases providing active CDSS were available from the five GP computer system suppliers. Two provided their own active CDSS whilst the other three hosted third party CDSS provided by the company First Databank Europe. In addition all of the GP clinical systems allowed users to add electronic manual reminders or alerts to a patient record that would appear when a patient record was accessed. These alerts could be authored with free text to reflect a specific clinical intervention or to add a simple reminder or message.

**Table 3.8 Current profiles, usage and characteristics of CDSS available to use by GPs**

<b>Active CDSS</b>	<b>Characteristics</b>	<b>Passive CDSS</b>	<b>Characteristics</b>
First Databank Europe	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	e-BNF	Electronic access to the British Nationally Formulary (BNF).
Script-Switch	Point of prescribing decision support tool providing locally authored messages via prompts to inform on cost effective drug choices, safety warnings or other relevant prescribing related information	INR-Star	Supporting anticoagulation management and therapeutic dosing of warfarin
Prescribing Plus	Point of prescribing support tool when initiating acute and repeat prescriptions by suggesting safe, appropriate and cost efficient alternative medications.	NICE Clinical Knowledge Summaries (CKS)	Summaries of the current evidence base and practical guidance on best practice in respect of over 300 common and / or significant primary care presentations
EMIS (GP System Vendor)	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	NICE Guidelines	Independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation
INPS (System Vendor)	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	EMIS Mentor	A comprehensive resource to provide details about disease presentation, diagnosis, investigation and management. A portal for education, research and personal development.

**Table 3.8 Current profiles, usage and characteristics of CDSS available for use by GPs (cont.)**

Active CDSS	Characteristics	Passive CDSS	Characteristics
Micro-Test (First Data Bank)	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	DXS	Enables recommended content such as care pathways, medicines, referrals, patient education and support groups at the point of prescribing.
SystmOne (First Databank)	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	BMJ learning	Provides accredited, peer-reviewed learning sessions in text, video, and audio formats.
I-Soft (First Databank)	Drug Database: CDSS for drug interactions, warnings, contraindications, dose checking, allergies and duplicate therapy	CHADS 2	Simple audit tool used in primary care to aid the risk stratification and effective management of Atrial Fibrillation (AF) patients, in order to reduce the risk of stroke
QOF Alerts for QMAS data collection	QMAS is a national web-based software tool developed for implementing the current GP contract. Data from GP practices is aggregated to maintain patient confidentiality, and a set of quality (QOF) scores is calculated. An alert appears when a patient record is accessed reminding the user only where specific clinical interventions are required to meet requirements as stipulated in the GP contract.	Q-Risk	Calculator to work out the risk of having a heart attack or stroke over the next ten years

**Table 3.8 Current profiles, usage and characteristics of CDSS available for use by GPs (cont.)**

Active CDSS	Characteristics	Passive CDSS	Characteristics
		PCT Extranet website	Extranet site that provides access to prescribing support produced by the medicines management team such as prescribing newsletters, guidelines and links to external websites.
		Health Numerics	An analytical tool that combines disparate data sources to provide a single view of healthcare activity at patient and population level.
		Map of Medicine	Supports the optimisation of care by providing access to comprehensive, evidence-based guidance, and clinical decision support at the point of care
		Medicines Complete Set	Electronic access to some of the world's leading drug and healthcare references from both the publishing organisation and selected partners
		General Practice Notebook	An online encyclopaedia of medicine that provides a trusted immediate reference resource

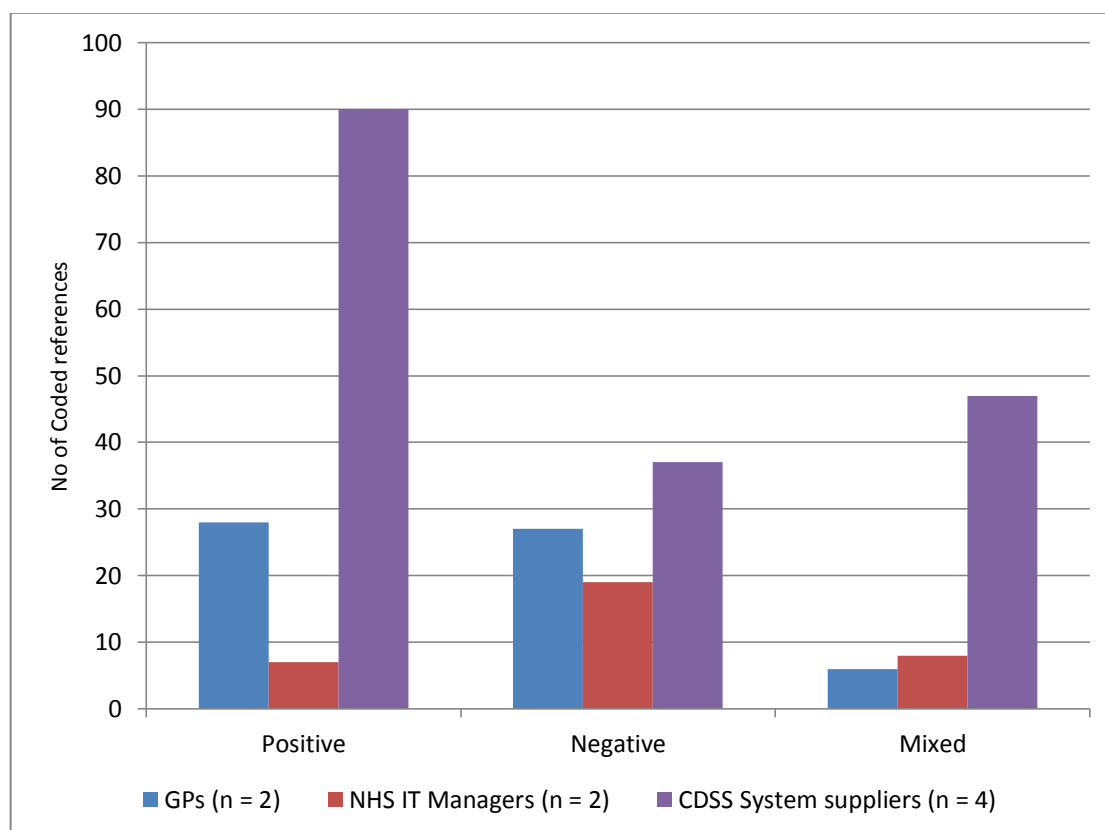
**Table 3.8 Current profiles, usage and characteristics of CDSS available for use by GPs (cont.)**

Active CDSS	Characteristics	Passive CDSS	Characteristics
		National Prescribing Centre (NPC)	The NPC (now part of NICE) is an on line resource that provides a wide range of resources (including e-learning) and arranges activities and events to support and promote evidence-based medicines management across the NHS, to help improve patient care and service delivery
		Patient.co.uk	On line resource that provides evidence based information on a wide range of medical and health topics to patients and health professionals in the UK

The actual numbers of passive CDSS available was described by one informant as “countless”. Internet access and availability to all GP practices has meant traditional paper based resources such as journals and guidelines are now available electronically. In addition primary care organisations have made available to general practice local extranet portals for dissemination of a wide range of resource and support information for general practice to include prescribing and medicines management support. Passive CDSS that were identified offered a range of features aimed to support decision making in range of clinical situations and points within care or treatment episodes. These included support at the point of prescribing, during patient consultations, clinics or non-clinic situations e.g. personal learning.

### 3.10.1 Views and experiences of CDSS in primary care

Overall mixed or negative perceptions and experiences outweighed positive ones for the GPs and NHS IT managers compared to the CDSS informants. Figure 3.6 shows the views and experiences of informants on CDSS in primary care by stakeholder group



**Figure 3.6 The views and experiences of CDSS in primary care by stakeholder group.**

### **3.10.1.1 GPs' views and experiences of CDSS**

Overall both GPs expressed mixed opinions of CDSS citing both positive and negative views and experiences and these are shown in Box 22. A number of positive experiences aspects to CDSS were cited, included cost saving alerts, reminders about drug interactions and monitoring, and the on - going alerts and reminders provided within GP systems to support QOF. However a major problem that was specifically described was CDSS and over-alerting, and that most active alerts were ignored.

#### **Box 22: GPs' attitudes towards CDSS**

GP1: "I certainly find it very useful, simple reminders to check.....for liver function tests for example, or if somebody is on methotrexate, you know an alert that warns you about that is extremely useful.....drug interactions.....a lot of the alerts I think are probably fairly routinely ignored because they are recognised interactions or they are beneficial interactions so for example if you add one anti-hypertensive to another and the alert tells you it's going to cause hypotension that's exactly the intention, and I think that can lead to.....perhaps a sort of malaise really you know then people don't not pay enough attention when they really are significant, like LFTs or methotrexate."

GP1: "You know I think active is more, is more useful, I think in terms of commencing new medication, then the passive I think systems are appropriate.....but repeat prescribing I think active methods would be, would be because it's simply you know the speed, the time that it takes, If I am starting a new medicine I would look it up, look at the monitoring requirements, look at its dose, make a decision, but it's around repeat prescribing, where the active alerts are much more useful I think."

GP2: "So within the clinical systems in use they have all got it to an element and I have to say that most of them implement far too many messages to the point that I ignore most of them.....so there some times when the message becomes overly laborious especially if you get it several times and that would be an example where I think the information becomes less useful so I often wish that the messages that you know where you can turn off for the next 10 times so you only get it one in 10.....just so you don't get flooded by it."



**Box 22: GPs' attitudes towards CDSS cont.**

GP2: "I have colleagues who definitely just ignore the whole process.....actually I don't think in practice, I know I just talk to people that say I hate that Script-Switch and it's just a delay in issuing that drug."

GP2: "It produces you know prompts we use for QOF which essentially is decision support, which reminds us of all the stuff to do, and without that I am convinced our QOF target would slip by 20%.....I think they are fantastic, and I use that now.....I will add reminders into that for other things, perhaps they need a colonoscopy 3 - yearly.....we use the same system to remind us."

**3.10.1.2 NHS IT managers' views and experiences of CDSS**

Overall the NHS IT managers described mostly negative or mixed experiences of CDSS in relation to both technical aspects of CDSS and also practical difficulties such as the effect on the running of GP practices and these are shown in Box 23. Some of the problems with CDSS were the way systems were used by GPs, management issues, over alerting and technical difficulties such as integration with the GP clinical system. In contrast positive aspects to CDSS included their use to provide safety related warnings and alerts.

**Box 23: NHS IT managers attitudes towards CDSS**

IT1: "The problem with something like that is that the user needs to change their mentality or the way they are thinking or using the application.....the training side of it is simple, it is very easy to use; but if they don't want to use it they can override it and if they switch it off what happens is they continue to work as normal.....at the moment a lot of these third parties are going out and developing products and tools that do not integrate and that's where a lot of these are failing or not working"

IT2: "They (GPs) find them (pop up boxes and warnings) annoying, some of them do, because they just want to do the prescription and get the patient out of the door, they've got ten minutes.....I don't think they pop up too much, they pop up at the relevant time but it's just down to the fact that GPs only have a certain length of time.....you can't have too many of these if it's a contradiction for a medication for a patient.....it's far better to get too many boxes than for someone to miss it because they have had only one box pop up."

**Box 23: NHS IT managers attitudes towards CDSS cont.**

IT2: "If they have a contraindication for penicillin.....it might be on the record but they are so busy doing the consultation and then suddenly it flags up..... do you realise that you have prescribed something that the person is allergic to?.....it's patient safety at the end of the day."

**3.10.1.3 CDSS informants' views and experiences of CDSS**

The CDSS informants described considerable experiences of CDSS in primary care and although limited some experiences within secondary care. In primary care a range of positive features were described in relation to the benefits of both active and passive CDSS and these are shown in Box 24. These included the provision of clinical information to support prescribers, ease of implementation, and time saving for end users. Good examples were provided highlighting clear advantages of both active and passive CDSS. Some drawbacks were described such as promoting wider usage particularly with passive systems.

**Box 24: CDSS informants and positive experiences of CDSS in primary care.**

DS1: "There are some very good passive resources in terms of websites, internet resources that are used in a lot of settings but of course they do rely on the clinician going to them.....I can see that passive systems have real benefit for dissemination of local information that would be of benefit to prescribers, the question of how to promote their use is a difficult one."

DS2: "In primary care I don't think there is a doctor that doesn't have a clinical decision support system, how much they rely on it and how much they use it and how far they take it is more individual, but I think they are all using it to some extent at least.....dose and dose range check.....the normal dose of this drug is within this range, the dose you have prescribed is too low so it is likely to be ineffective or the dose you have prescribed is too high."

DS3: "So interactions, contraindications, precautions, prescriber warnings, drug doubling, allergy checking and so on.....so that work was done primarily in the 1990s.....all the GP system suppliers do very similar sorts of things there is not a big difference between us and anyone else."

**Box 24: CDSS informants and positive experiences of CDSS in primary care cont.**

DS4: "Yes so the key thing around Script-Switch is that it is an active process it pops up automatically, it interrupts your workflow.....and presents you with choices you have to think about, but it is a very quick process.....so the second group of messages are the information messages.....for example it can say this drug is not in the formulary and here is the formulary and give you a html link to the formulary so it is presenting context and information to the clinician."

As with the GPs and IT managers a specific area of concern was the problem with over alerting and having to override alerts. Box 25 shows experiences of the CDSS informants in relation to CDSS and over alerting. DS4 described changes in attitudes towards CDSS from a GP perspective in terms of being challenged around decision making and the clinical freedom to prescribe and that over time this situation has improved and CDSS is now seen as beneficial.

**Box 25: CDSS informants and experiences of over-alerting**

DS1: "You know there are two ends to the spectrum.....are you to provide no decision support at all, so for example one electronic prescribing implementation in this country that chose to do that.....they said we are not going provide any decision support because then our users will know there is no decision support, they will use their brains rather than rely on the computer.....and if they miss it.....it's their fault but on the other hand you can provide a system that provides an alert for every single clinical detail, every minor interaction, every possible allergy to an excipient and so forth, in which case you know you end up with clinicians ignoring most of it simply because there's just too much."

DS3: "Feedback from GPs is that they get too many prompts and they override them.....they override most of the prompts, occasionally they will take notes of the prompts but most of the time they override the prompt.....you get alert overload.....and you ignore all of them and that's the danger."

DS4: "So I think there has been quite a transition, over the years, when they first came in.....it mirrors actually I think the conversations that are going around what is the role of the clinician.....so when they first came in I remember conversations with my colleagues of mine.....what's this piece of software telling me how to do my

**Box 25: CDSS informants and experiences of over-alerting (cont.)**

job?.....I think it used to be seen as that whereas there is an acceptance now that the clinical variation was seen as a quirk but now it is seen as an issue, but people now see decision support as a way of protection and for the patient.....and now I see people who say.....that saved my bacon.”

**3.10.2 Developments and improvements of CDSS in primary care**

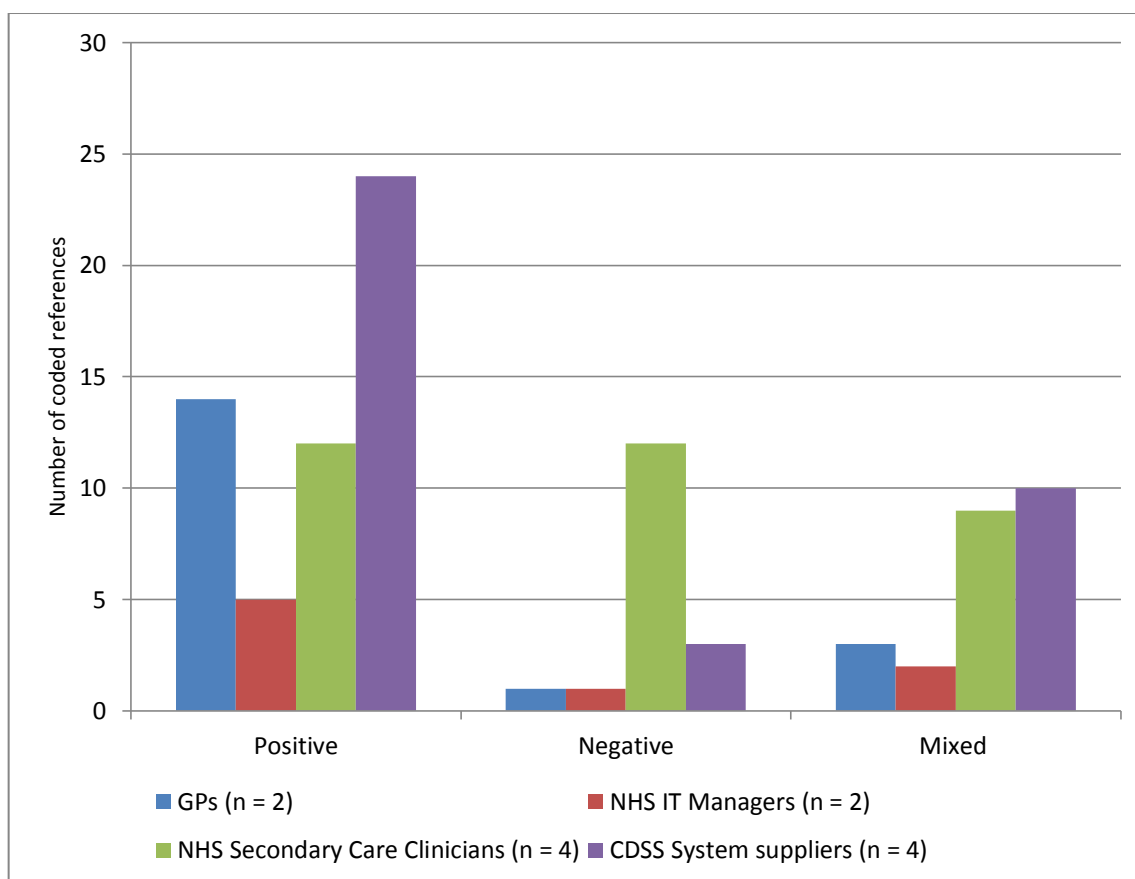
In addition to drug safety warnings and alerts some of the informants described a range of current developments supporting both prescribing and disease management in general practice to include:

- Drug dosage information (dose setting and clinical indication)
- Drug dosage management (dose optimisation)
- Disease management and care pathways to include diagnostics and investigations
- Electronic prescribing systems in secondary care
- Supporting linkages between GP clinical systems and community pharmacy clinical systems

The informants described specific examples where they felt current CDSS could be improved. These areas included improvements in the management of blood test results, provision of patient information leaflets, and prescribing support in the use of high risk drugs. In addition one of informants described how one CDSS available in the USA that could potentially be developed further in the UK, specifically to prioritise the importance of QOF alerts in relation to specific therapeutic conditions.

**3.10.3 Specialist drugs and CDSS**

The concept of developing a CDSS to support GPs in the use of specialist drugs instead of the current paper based model using shared care protocols was explored with all of the informants. Overall the concept was met with positive responses across all stakeholder groups and these are shown in Figure 3.7.



**Figure 3.7 Views and attitudes for a CDSS to support the use of specialist drugs by stakeholder group**

### 3.10.3.1 Views of GPs

Both GPs provided positive feedback to the concept and as potential end users described potential operational models and this shown in Box 26. Although a preferred model was an active alerting system based on the QOF model a concern was raised over being able to trust the system.

#### **Box 26: GPs' attitudes towards CDSS to support the use of specialist drugs.**

GP1: "I think it would have to be cross boundary.....I think a true shared care protocol should be that, and it's okay us having our own primary care system, but it would be much better probably if something like INRstar, if it was web accessible and the hospital consultants had to access it as well."

**Box 26: GPs' attitudes towards CDSS to support the use of specialist drugs cont.**

GP2: "So the advantage is if it was an independent module, it would remind you because it only comes up with these drugs of the importance of what you were doing, it would focus the mind which I think is good.....I think the advantages hopefully that it would reflect a standardised protocol, although that might not reflect the protocols in the shared care agreements, I often look at the shared care agreements and often wonder why there can't be a standardised shared care protocol."

GP2: "An alert, it would come with my other alerts, the QOF alerts as they are the ones we used to interacting with and working with as opposed to, let's say if you went in the screen with drug interactions that's the one I know that none of us ever read as there is too much there.....yes you would over trust it.....you have just issued the azathioprine without a second thought because the box was yellow."

**3.10.3.2 Views of CDSS informants**

All the CDSS informants were positive towards the concept of a CDSS supporting GPs in prescribing specialist drugs and these views are shown in Box 27. It was accepted that from a technical perspective that the concept was ahead of the current capabilities of IT systems. A number of examples were described of how operationally the concept could support end users. Overall an active alerting CDSS was the preferred model that would benefit end users particularly built around key safety features.

**Box 27: CDSS informants and attitudes towards a CDSS to support the use of specialist drugs.**

DS1: "What would be really good is for someone to do some work on the development of a shared care protocol in an electronic format that is hyperlinked in such a way that if there were routines running behind that would be absolutely brilliant, but that represents something a bit of a way ahead of where we are at."

DS2: "Eventually moving towards active formats will become safer for patients because if you say you had been asked to prescribe Mr Smith repeat tacrolimus and he has not had a blood level for 3 months, I need to see him.....the system can alert if he has not got a current blood level and it can also then alert.....using INR as an example say it has to be between 2 and 3.....it can flash an alert up to say it's 3.4 make an appointment.....it's 10 ring the patient immediately."

DS3: "I don't think any of the systems actually do that today, though they may have the potential to do it if they are individually customised by the end users.....with any national guidance for how to do that.....you could set up reminders and alerts for the patient based on the fact that they are taking this drug, so support prompts for the user would appear."

DS4: "In an ideal world you would actually have an electronic shared document that goes between primary care and secondary care and until that document flag is on the record you as a GP can't prescribe it.....I would always go for an active format for the simple reason that it reduces the number steps that can go wrong.....so if for example you had an active block on that drug unless there was a shared care process in place and you physically had to override that and sign that put an explanation to why you were overriding it that process it would add a level of safety around it."

**3.10.3.3 Views of NHS IT managers**

The NHS IT managers were also supportive of the concept of CDSS to support use of specialist drugs and their views are shown in Box 28. Both NHS managers preferred an active system and also highlighted the need to ensure adequate training and that the CDSS would need to be integrated within the GP clinical system.

**Box 28: NHS IT managers and attitudes towards CDSS supporting the use of specialist drugs**

IT1: "I think an active system would be better, a passive system.....there already is information available to them I don't see the GPs going to use it.....it has to be active, it's got to be easy to use.....because these guys they don't want to go out for training they have not got the time, they are very negative towards any kind of training.....if it's structured in the correct way and organised with the right people and the relationship is there with the GPs themselves, that's what makes it successful.....and I think.....I would be quite positive about it.....I think it's a very good move."

IT2: "If it's part and parcel of the clinical system (integrated).....let's say if it's a different type of drug, then you haven't got the problem.....it will flag up there is an issue, but if you go in separately it may not flag that up for that person necessarily so it needs to be combined with the clinical system."

**3.10.3.4 Secondary care clinicians**

Box 29 shows the views of the secondary care clinicians towards the concept of CDSS supporting the use of specialist drugs. In contrast to the other key informants the secondary care clinicians raised some concerns over the concept such as over-alerting, multi-user access and the ability to amend or delete records. A specific area of concern was the level of patient monitoring required including the need to manage drug interactions. It was also felt that if GPs were to manage this they (GPs) would need to run transplant clinics in primary care.

**Box 29: Secondary care clinicians' attitudes towards CDSS in supporting the prescribing and monitoring of specialist drugs**

NHS1: "Thinking of a web based technology.....that's a very neat solution in terms of.....from what I understand of it you are talking about a single record that all parties could access it and understand that would have a lot of merit."

NHS2: "It would also depend if we could amend it at our end or if it was view only at our end.....we would need to be able to access it, but also to realise that there may be errors in the medication list, especially with the regards to immunosuppressant, so we could actually change it ourselves and then we could ping a note to the GP to say that we have amended Mrs Smith's immunosuppression records."



**Box 29: Secondary care clinicians' attitudes towards CDSS in supporting the prescribing and monitoring of specialist drugs cont.**

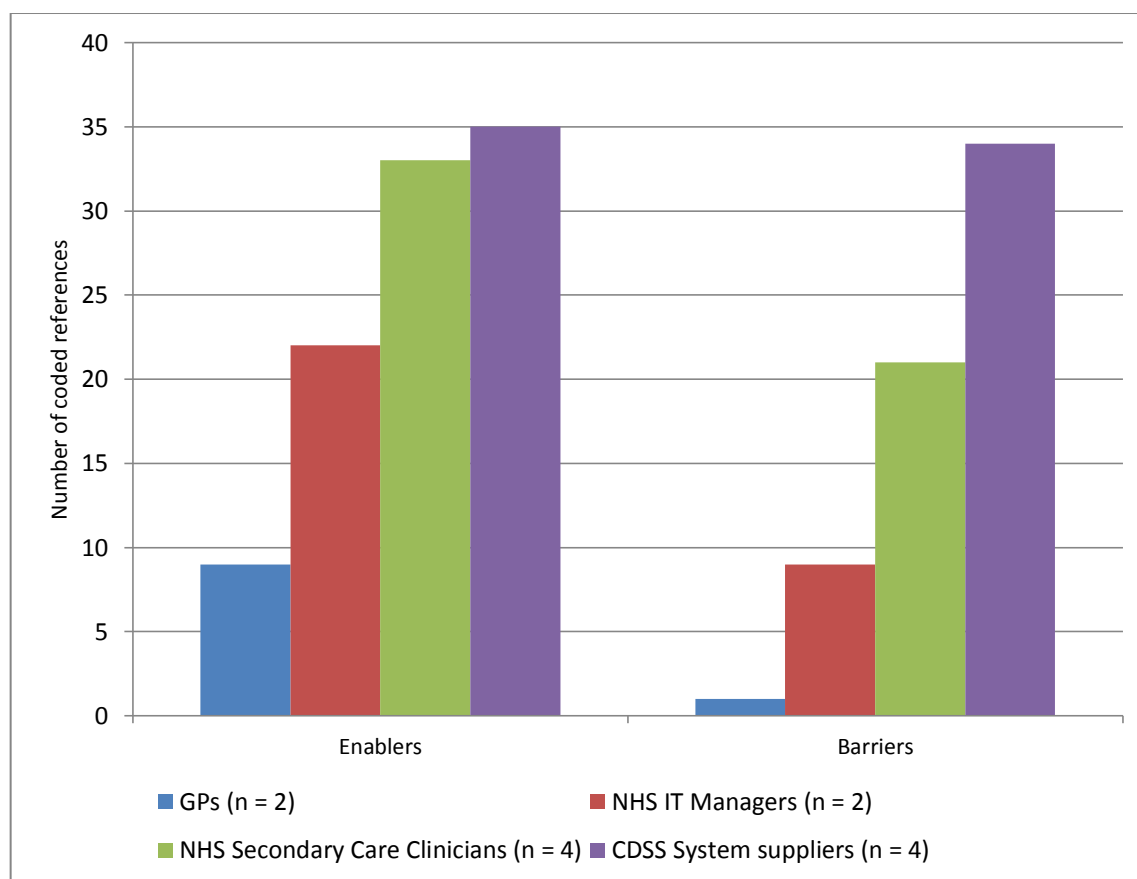
NHS3: "All of the monitoring for our patients gets done within the transplant clinic and you know in a way, the GP role tends to be to issuing prescriptions.....but I think one of the biggest issues is going to be drug interactions."

NHS3: "The difficulties is setting two defined parameters for the use of these medications and also repeat prompts if every time you prescribe mycophenolate it tells you to check white cell count or something like that will just be ignored over and over and over again.....It would be a very good idea if.....you could make the two databases talk to each other.....the question is who would override what?"

NHS4: "In order for it be fair to a GP you would have to build in a very high level of supervision in terms of checking.....basically calling the patient's back to have their renal function checked and their levels checked after dose changes.....you are basically asking the GP to run a transplant clinic and I think that would be a lot to ask.....clearly transplants are about life sustaining organs.....livers, hearts and lungs if you get that wrong then it's good night Vienna."

**3.11 Developing a novel CDSS to support the use of specialist drugs**

The informants discussed what would support the development of a CDSS in this area and what would be the potential pitfalls that would need to be avoided. A range of enablers and barriers were described to include functionality, funding and key aspects around the developmental and implementation process. Figure 3.8 summaries these by stakeholder group. Table 3.9 shows enablers and barriers for a CDSS to support the use of specialist drugs by key informant.



**Figure 3.8 Enablers and barriers for a CDSS to support the use of specialist drugs by stakeholder group.**

**Table 3.9 Enablers and barriers for a CDSS to support the use of specialist drugs by key informant**

<b>Enablers</b>	<b>GP1</b>	<b>GP2</b>	<b>NHS1</b>	<b>NHS2</b>	<b>NHS3</b>	<b>NHS4</b>	<b>DS1</b>	<b>DS2</b>	<b>DS3</b>	<b>DS4</b>	<b>IT1</b>	<b>IT2</b>
Multi-user access	✓	✓	✗	✗	✓	✓	✗	✓	✗	✗	✗	✗
CDSS: Active alert	✓	✓	✗	✗	✗	✗	✗	✓	✗	✓	✓	✓
Ease of Use	✗	✓	✗	✗	✗	✗	✗	✗	✗	✓	✓	✓
Joint development and Implementation	✗	✗	✓	✓	✓	✗	✓	✓	✗	✓	✓	✓
Patient involvement	✗	✗	✗	✗	✓	✗	✗	✓	✗	✓	✗	✗
Data quality and functionality	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✗
Use of existing systems and frameworks	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓	✓	✓
<b>Barriers</b>												
Integration and data quality	✓	✗	✗	✗	✗	✗	✓	✓	✗	✗	✗	✗
Security and regulation	✗	✗	✗	✓	✓	✗	✓	✓	✗	✓	✗	✗
Implementation	✗	✗	✓	✗	✗	✓	✓	✓	✓		✓	✗
Needs of end users	✗	✗	✓	✓	✓	✗	✗	✗	✗	✓	✓	✓

### **3.11.1 Enablers**

In order to support the development of a CDSS in this area a range of key functionality features and characteristics were described by the informants. In addition a number of additional developmental aspects were identified to support implementation.

#### **3.11.1.1 Multi-user access**

A key aspect to support a CDSS in this area expressed by the informants was the need for the availability of access to a single electronic patient record by a range of end users based within both primary and secondary care (See Box 30). The informants provided specific examples of how this could help such as by having a single medication and pathology record, and the potential to extend user access to both patients and community pharmacists.

#### **Box 30: Key informant views on multi-user access**

GP2: "So ideally the secondary care clinician and I would have access to the same record, and ideally.....they would know, we would both know when the drugs were issued and we both share that information.....actually more immediately possible is that we would share the same pathology history."

NHS3: "The other issue is that some form of accessible electronic data to also allow that patient to have access, so when Joe Bloggs pitches up in a hospital in the outer Hebrides he can log in and say look there are all my medications and there are all my problems and these are all the issues.....there are things like over the counter medications.....the pharmacist also needs to check what they are giving out is correct.....and that it's being prescribed from maybe a different system."

NHS4: "I would want to be notified when changes were made so I could keep track of that and the rational thing for us in primary care is to have some shared medication management system so I could see what was on their system and they could see any changes that we make."

### **3.11.1.2 Active alerts**

Active alerts were the preferred functionality for a CDSS with a range of advantages described by the informants (See Box 31). Both GPs described the need for an active alert to appear at the point of prescribing. A number of suggestions of how the alert appeared made such as the current QOF alert, a flashing alert as it acted as a reminder and a combination, with the initial alert being active but incorporating some passive components.

#### **Box 31: Key informants and views on an active CDSS alert**

GP1: "I think the priority for me would be to have.....you know if for example if the shared care protocol is presented to me at the time of prescribing, at the point of prescribing, it's no good having some dim and distant website, somewhere having to trawl through for every drug, every indication, that is useless."

GP2: "An alert, it would come with my other alerts, the QOF alerts as they are the ones we used to interacting with and working with as opposed to, let's say if you went to the screen with drug interactions.....that's the one I know that none of us ever read as there is too much there."

DS2: "If there is something that needs to be done right now as this blood test has come back and it's flashing up on his screen, it's much safer for the patient, more effective than having to say here are your repeat prescriptions but oh I haven't got a blood test when did I have one?"

DS4: "I think a combination.....there has to be active pop up which says that there is an issue that you need to resolve, and there could be some passive processes that you just tick and go through.....you know.....I have provided him the leaflet on azathioprine, you can have a passive process for that and you just tick the box."

IT1: "I think an active system would be better.....a passive system.....there already is information available to them I don't see that the GPs are going to use it"

IT2: "Because you are not logging in separately.....if it's part and parcel of the clinical system.....let's say if it is a different type of drug, then you haven't got the problem....it will flag up there is an issue, but if you go in separately it may not flag up for that person necessarily so it needs to be combined with the clinical system."

### **3.11.1.3 Ease of use**

The ease of use of a CDSS was a key feature that was described by the informants (See Box 32). This was described in relation to GPs and the individual level of aptitude towards IT and time constraints in use during patient consultations.

#### **Box 32: The views of key informants on CDSS ease of use**

GP2: "The other aspect is that it is instinctively usable so that my colleagues who don't like computers are not even aware that anything has changed.....so they say oh look, oh yes, good I'll do it, rather than we add another box.....a bit of software that they have got to configure on the computer, so it will just fail with all those important people."

IT2: "Easy to use.....quick to use, easy and quick.....and at no cost to the practice."

DS4: "It has to be intuitive.....it has to be minimally intrusive unless where it needs to be intrusive, so it shouldn't take me 15 minutes for me to something where previously I would do in 2 minutes."

### **3.11.1.4 Joint development and implementation**

Box 33 shows some of the views from the informants that describe gaining support from a range of stakeholders in primary care, secondary care and professional bodies. The secondary care clinicians described joint development with primary and secondary care but also the need for a clear demarcation of roles and responsibilities and the importance of a locally developed project that could be piloted. The IT managers described implementation from a primary care perspective in terms of a working knowledge of GP clinical system suppliers. A specific aspect to support implementation was to work alongside GP clinical system suppliers rather than developing anything independently.

#### **Box 33: Key informants and views on joint development and implementation**

DS2: "It's getting all the people who are going to be stakeholders, so the secondary care initiator and the primary care continuer and possibly the community pharmacist or whoever is going to be looking after the clinics."

DS4: "The key thing would be engagement with the end users.....yes the end users, so how is it going to impact them, and how is it going to benefit them?"

**Box 33: Key informants and views on joint development and implementation cont.**

NHS2: "I think the whole system would have to be developed between primary and secondary care with input from both sides so it would do what we wanted it to.....and I think both sides would have to sign up to still who has responsibility for what."

IT2: "You would have to approach each of the individual system suppliers and say this what we want to.....can you do it for us.....and then they will decide, and of course as soon as the one has done it the others will follow suit because if it's got something the others will want to offer it to their customers."

**3.11.1.5 Patient involvement**

The need to engage with patients was described in relation to both the development of and eventual use of a CDSS in this area and this is shown in Box 34. The informants described that patients would need to be convinced of the advantages of any new system, and that a CDSS may only be suitable for certain clinically suitable patients. Patient involvement was also described in terms of service developments.

**Box 34: Key informants and views on patient involvement**

DS2: "So it is patient perception, you have to be able to convince patients that this is in their best interest."

DS4: "I think you need to go one step back, patient eligibility, which is you need to be able to demonstrate that you have picked the right patient.....I think the key is how you engage with the patient on that, and actually I am keen that you actually have that debate with the patient."

NHS3: "So bottoms up and also patient centric.....a lot of the changes we have made over the years we have always tried to involve the patients with it."

#### **3.11.1.6 Data quality and functionality**

The quality of clinical data to be presented to end users was described by the informants as a key issue in terms of CDSS functionality. The informants described the importance of key safety features specifically around drug interactions, dosages and clinical support for end users and are these shown in Table 3.10. In addition two key expert functions were described that would support GPs to include symptom management and organ graft management.



**Table 3.10 Key functionality for a CDSS to support the use of specialist drugs**

Key Functionality	Key Informants
Drug interactions	<p>DS1: "I think the key things would be to ensure that the patient pathway is as smooth as possible in terms of prescribing and supply and to ensure top line safety around major drug interactions."</p> <p>NHS3: "I think that the issue of interactions and alerts for both patients and for GPs and secondary care as well....you know because it's not just the consultant adding in its other people in the hospital adding on drugs."</p>
Drug dosing, side effects and toxicity	<p>DS3: "They will need to know dose information, how it interacts with other drugs the patient is taking, they need to know information about its toxicity, and what monitoring they have to do as a result of that and so on."</p>
Drug monitoring	<p>GP1: "Safety really.....safety and monitoring, we trust our colleagues in the hospital to choose the drug appropriately, the indication you know, they make the decision about the commencement of therapy, the indication and GP's role I see it maintain safety and monitoring."</p> <p>NHS1: "Probably all things we talked about in terms of what is a good shared care protocol.....when to do tests, what actions need to be taken as a consequence of those.....those monitoring parameters, support that would stop you making errors in terms of prescribing doses....that kind of thing."</p>
Symptom linkage to use of specialist drugs	<p>DS4: "So if you had a symptom finder, so if you had a record that said OK, the GP had just read coded sore throat, temperature.....and it was flagged up and it came up with a proactive alert to say.....oh, shortness of breath.....anti-TNFs are you aware that this is a complication.....then I think GPs would be a lot happier."</p>
Knowledge of graft function	<p>NHS4: "It would need to know about graft function.....there would need to be a connection through to a clinical module.....so other drugs we check levels of say digoxin.....it's not just to adjust the dose to keep the digoxin within a certain range so imagine a system that knew what the patient's heart rate was.....so you got to keep the drug within this range but you also have to keep an eye on what the heart rate is."</p>

### **3.11.1.7 The use of existing systems and frameworks**

Box 36 shows some of the views of the NHS IT managers that suggested that one way forward was to make better use of current IT systems and frameworks and to work with GP clinical system suppliers particularly with the current movement to hosted systems.

#### **Box 36: NHS IT managers and views on the use of existing systems and frameworks**

IT1: "There has been a huge investment in this core network that ultimately BT own.....N3, it's one of the biggest networks in the UK, so it's just not being used to its advantage, we are only using 10%.....if the right applications come to the table.....EMIS and SystmOne are making use of it but where you are going in and installing it things locally in isolation it's a backward way of working now, these guys should be making better use of this network, putting something here which allows all parties to talk to each other."

IT 2:"Yes because that's where we are moving away from (non-hosted systems) and there is no point trying them."

Box 37 shows some of the views of the CDSS informants that highlighted previous attempts to develop CDSS and the existing technologies that could be utilised. It was identified that two GP clinical systems were now able to allow multi-user access that could potentially be explored as a way of incorporating a CDSS in this area.

#### **Box 37: CDSS informants and views on the use of existing systems and frameworks**

DS3: "There have been lots of attempts at this.....this is not revolutionary thinking.....there is a HL7 standard called Arden Syntax which is about this precise thing which enables you to encapsulate this decision stuff in an electronic messaging format that you could transfer between systems."

DS3: "This is a very specialist area and the investment required for which there is very little payback for the customer.....it becomes a financial question it does not become a technical question.....these things are achievable and they are achievable with the technology we have today."

**Box 37: CDSS informants and views on the use of existing systems and frameworks cont.**

DS4: "So EMIS Web has a distinct primary care record that is held by primary care and it's able to communicate certain packets of information with other people.....whereas with SystmOne there is a single record and the ability is to view parts of that single record depending on your context, so it is context sensitive viewing.....there are pros and cons when you get into both."

**3.11.2 Barriers**

A range of barriers to both the development and implementation of a CDSS were described by the informants. These barriers highlighted key concerns around safety, data quality, clinical responsibility, IT issues, medico-legal issues, communication, relationships with secondary care and cost.

**3.11.2.1 Integration and data quality**

Concerns around the quality and accuracy of clinical data were raised by the informants and are shown in Box 38. These included problems with consistency and standards around prescribing terminology and the accuracy of records held in hospitals compared to GP systems. GP1 also raised the issue of integration with secondary care systems and for hospital based clinicians accessing a single record.

**Box 38: CDSS informants and views on integration and data quality**

DS1: "I know there a lot of people sweating on how you deal with consistency and standards for prescribing terminology.....and it is not an easy problem to solve..... one of the potential risk areas, and it shouldn't be the case but I know certainly it has been the case in the past, but quite often products initiated in hospitals have not found themselves on the GP clinical system."

DS2: "It depends if you wanted it to be used stand alone or integrated with the whole patient record.....If you wanted it integrated with the current patient record, the problem becomes that the current GP record and the hospital record are not at the moment going to be identical."

GP1: "Disadvantages would be the usual IT burden, you know how you could integrate with primary care systems, how you could allow consultants to access the record."

### **3.11.2.2 Security and regulation**

Box 39 shows concerns raised by the informants around security and regulation. The CDSS informants highlighted issues in relation to the design of the database, confidentiality and potential problems such as medico-legal issues. The secondary care clinicians also described issues around security with patient data and also with the ability to override database entries. Neither of the GPs expressed concerns over security and regulation.

#### **Box 39: Key informants and views on security and regulation**

DS1: "Security and information governance, using appropriate algorithms and terminology, how you deal with communication from secondary care and you instantiate that into systems that are familiar.....or how this presented in ways that are acceptable to the end user either in primary care or in secondary care."

DS2: "There are always risks about the other data, patients won't be very happy if they have had a renal transplant.....the concept on the spine around a brown paper envelope.....don't say I have got HIV.....but I am taking ritonavir, saquinavir.....and the others.....so you are not going to have anything else."

DS4: "There are going to be some issues and there are some medico legal things.....so for example if I am viewing the record and someone else is updating it at the same time and then I go back and somebody says well you missed something in that record."

NHS2: "I can think about some of my patients who get a bit funny about anybody accessing their records, I have got one guy even when I tried to sign up for homecare.....he succumbed eventually.....that would mean there is a company out there that would know what tablets I am on.....but people can break in and interrogate the system and I am a transplant patient."

NHS3: "The only issue is would they want me to override their database.....would I want someone from primary care overriding the database?"

### **3.11.2.3 Implementation**

The informants described a range of potential barriers for a CDSS in this area from an implementation perspective and these are shown in Box 40. The CDSS informants highlighted financial constraints, a lack of political support from stakeholders and a reluctance from secondary care due to the vastly different uptake and level of IT infrastructure compared to primary care. In addition another issue identified was establishing a working relationship between third party or external providers of CDSS with GP clinical system providers. The secondary care clinicians also highlighted a problem with IT infrastructure in secondary care and gaining widespread support from GPs as not all GPs would have renal transplant patients registered at their practice.

#### **Box 40: Key informants and views on implementation**

DS1: "The real issue is the political will to do it.....we have this huge issue around diabetes, or people being admitted with hypos, and this huge issue around falls, they will say woo!!...yes!!.....but actually.....the extent of monitoring immunosuppressants is not sexy enough and not political enough."

DS2: "Primary care is very adapt to electronics.....so if the hospital that is initiating the care is reluctant and is heavily paper based and particularly if the team working in that area, in that hospital.....convincing them could be difficult."

DS3: "Because everyone would say yes and would definitely want one, because it is a really difficult area and you would need help.....you are not going to have a problem with demand so how much?" (cost)

IT1: "The barriers would be there from the big players the clinical applications out there in the practices, EMIS, Vision, SystmOne.....the barriers would be for them for allowing these new guys, this company coming along with this product to talk to them and say yes we can make it work with our product, if that link is not there it is going to be very difficult for it to work."

NHS1: "I think the barriers would.....around Trust IT architecture.....I mean in the sense that some Trusts take a very hard line on bespoke software packages you know.....so it's quite hard to introduce specific technologies."

**Box 40: Key informants and views on implementation cont.**

NHS4: "Those 1500 patients that I talked about we are talking about the whole region.....it's an awful lot of people and an individual GP practice will not have a dozen renal transplant recipients."

**3.11.2.4 Needs of end users**

A number of concerns were described in relation to end users and potential difficulties that could arise and these are shown in Box 41. The NHS IT managers described issues such as training requirements, GP time and a lack of engagement with support services. The secondary care clinicians described potential problems with the overriding of alerts and messages and where end users may start to use the system incorrectly.

**Box 41: Key informants' views on the needs of end-users.**

IT1: "Time is completely the key.....they don't have time to go out to training, and if you think about a practice as soon you take out a GP, they have to back fill with a locum.....because where I see a lot of these things falling, or a lot of tenders not even getting pass the starting block, is the question will be asked how will you support it, and a lot of the time they say we will wait for the user to contact us, but the mentality of the users is that if they can get away without using it they won't log a call."

IT2: "Resistance.....the GP, even if it's been incorporated into their clinical system they may not use it even if it's there."

NHS1: "It would really be interesting to talk to some prescribers about how they feel about for example alert messages, whether they are things that just cancel and ignore or whether there are things they take very seriously and then you get into the discussion about which.....you know, if we are going to wear people out with too many alerts coming on, which are the important ones that need to stay?"

NHS2: "It's all well having the support system there but if people don't know quite how to use it or start using it in the wrong way it would cause more havoc than it would solve."

### **3.12 Costs**

Financial aspects were described from a range of perspectives reflecting each stakeholder group and informant background. Some aspects of finance were specific such as expenditure on drugs or IT systems and software; however other aspects were service related and linked to funding for both primary care and secondary care. In addition both GP system and CDSS suppliers are all commercial organisations and therefore costs would be important in order to maintain profitability.

#### **3.12.1 Drug costs**

The four immunosuppressant drugs used in transplantation ciclosporin, mycophenolate, sirolimus and tacrolimus, until recently were all high cost patented medicines. Box 42 illustrates the views of the secondary care clinicians in relation to drug expenditure and renal transplantation. A specific issue raised was whether the actual costs involved had an effect on the decision to prescribe these drugs.

#### **Box 42: Secondary care clinicians and experiences of drug expenditure**

NHS 3: "You know they never actually said that it was too expensive, it was always a clinical reason or something, you know and I can understand that, they are expensive drugs.....if you have one patient on tacrolimus or mycophenolate that's probably blowing a £7,000 to £8,000 hole in your budget instantly for the patient and if they are Afro-Caribbean and they have got an adverse set of genotype you may be blowing £12,000 to £15,000 on one single patient."

NHS2: "It is interesting, sorry for being cynical.....there seems to be a correlation between the cost of the drug and the willingness or not to prescribe it, the get out clause is always that that it needs monitoring."

Drug costs were an important issue for the GPs and CDSS informants. Some of the advantages and benefits of GP clinical systems and CDSS were described in relation to promoting cost effective prescribing (see Box 43). The CDSS informants described the importance of drug costs in relation to GP prescribing budgets and how CDSS could support the management of this expenditure. A mixture of opinion was described in relation to the functionality of one specific CDSS, in terms of fully supporting GPs in clinical decision making.

**Box 43: GPs and CDSS informants' views of drug expenditure.**

GP 1: "I think certainly there are cost effectiveness benefits, for example yesterday I tried to prescribe orlistat, and the NICE guidance on orlistat was presented to me at the time a very quick exert, about one paragraph was presented at the time I tried to prescribe it."

GP2: "So the other thing to say that in Synergy, it gives a very good overview over pricing, much better than the other products out there, and I think in that perspective I get less out of it from a price perspective.....it's quite easy within Synergy to tell the different costs."

DS2: "They are more concerned with cost, whereas our future product that we are working with many customers at the moment including some of our competitor is not just based on cost, but is based on medicines optimisation."

DS3: "We know Script-Switch very well, they work with us, their functionality is designed to switch patient's prescriptions to, generally to PCT preferred options.....it's not done on safety grounds.....it's done on economic grounds so the PCT will say we want to stop GPs prescribing all these expensive drugs so they put on all these hooks, every time you prescribe one of those expensive drugs you get offered a cheaper alternative, you don't get offered something safer."

DS3: "Their business model is to sell their services to PCTs to reduce their prescribing budget, that's their economic model.....they can call it a decision support system, I would agree with that.....I would dispute the fact that it is clinically driven."

DS4: "I have a very strong interest in clinical and information governance and to me the education aspects of the tool and the safety aspects of the tool are just as important..... but in terms of the number of messages presented, if you are measuring it by that method, then cost saving is the largest utilisation and that will vary from dropping one drug to another drug or changing the formulation or the frequency of a particular drug or the numbers of a particular drug."



### **3.12.2 Service costs**

In the NHS in England the commissioning and providing of healthcare for patients are separate functions carried out by different types of organisation underpinned by a tariff based payment system for the provision of hospital based care and services. Introduced over a decade ago this system replaced the previous arrangements whereby hospitals were paid according to block contracts, and fixed payments based largely on historic funding patterns. A specific aspect of NHS service funding was described in arrangements to provide homecare services.

#### **3.12.2.1 Homecare services**

The cost of providing NHS services was an important feature not just from a safety perspective in relation to the use of immunosuppressant drugs, but from a financial position in terms of service delivery. The secondary care clinicians described the background to homecare services from both a financial and strategic perspective and some of the complexities involved in the decision making process (see Box 44). This initially proved difficult despite the problems with generic formulations. It was not until a national tender for immunosuppressant drug provision was announced that Homecare services were eventually agreed as a preferred supply route.

#### **Box 44: Secondary care clinicians' views of the financial aspects of homecare services.**

NHS2: "Yes, Healthcare at Home and Evolution are the two we use.....so Mrs Bloggs.....tacrolimus and mycophenolate.....dose is blah, blah.....20 weeks supply please and within 2 weeks they are delivered to their home."

NHS3: "Yes we then said OK we can try and use the homecare model..... there would be a small delivery charge for it but it would probably balance itself, but again they said no.....they wouldn't and it was not until the national tender came along and we all sat around the table and we said right what we can do is bring everyone back into secondary care, we can convert our patients to a generic brand and we can get everything at the national tender price and then all of a sudden it had to happen overnight for a benefit of about £2.5 million locally for our patients."

### **3.12.3 Funding of GP computers and IT Systems**

The current funding arrangements for general practice and IT systems, including CDSS were explored with the NHS IT managers and CDSS informants. With the backdrop of the current financial constraints in the NHS the impact on some of these

arrangements were explored in respect to funding arrangements for IT hardware and software. Box 45 shows current funding models as described by the NHS IT managers. The current funding model for GP clinical systems and CDSS were determined on local contractual arrangements with the NHS. A key feature that emerged was the reliance on NHS funding for GP IT system suppliers. Current financial pressures were also described as a key factor in the decision for changes whereby practices across a locality would be changing over to one GP clinical system.

**Box 45: Informants views on the funding of IT in general practice**

IT1: "I think a lot of that is funded by GPSOC, and by the PCT.....running costs, support maintenance, it does vary, certain products are supported.....some GPs have to contribute a percentage of the full amount, things like Docman, it does vary from Borough to Borough, it depends on what the GPs agree to as part of their framework with the PCT, funding does vary, from what I can see a lot of it is paid for by the PCT."

IT1: GPs are reluctant to pay or contribute towards anything to do with IT.....whenever they have asked for equipment they have expected the PCT to deliver, and the majority of the time they do, but where the PCT may feel that the request say it is to their advantage they ask the GPs to contribute they say no."

DS3: "GP practices who use our systems pay us a license fee and a maintenance fee for the software.....and that's what funds it.....very few of them pay us directly anymore, most of them get paid under a NHS contract with GPSOC to the PCTs and we get reimbursed in that respect.....so the site is registered as using our software and we get a fee usually via the PCT from them.....so it is all wrapped up in the software licensing fee."

DS3: "Script-Switch is not funded this way, Script-Switch is paid for by the PCT through prescribing budgets, DXS is funded primarily through pharmaceutical advertising.....so they sell their services to pharmaceutical companies so that when you go to prescribe something a little tiny advert, that big appears on the screen for the drug.....but the majority of the funding of any of these systems comes through the software licensing of our product."

### **3.12.4 Funding models for CDSS and specialist drugs**

Overall the informants had mixed attitudes towards funding arrangements for a CDSS in this area and these are shown in Box 46. The sums of money involved were described as considerable and a specific aspect that would require close examination particularly in light of current financial constraints facing the NHS. The informants described some of the broader aspects to funding arrangements highlighting the complex strategic relationships between stakeholder groups including central Government.

#### **Box 46: Key informants and views on funding**

DS3: "Hundreds and thousands of pounds.....probably several million by the time you have finished the project.....this is a very specialist area and the investment required for which there is very little payback for the customer.....it becomes a financial question it does not become a technical question.....these things are achievable and they are achievable with the technology we have today."

DS4: "You either go down a commercial route or you don't, and if you don't go down a commercial route then.....the history of the NHS is that it has tried lots and lots of things on a non-commercial route and they have either not been particularly robust, or they have not had buy in."

DS4: "And there are substantive costs, not just development but on-going maintenance of the product and the NHS has not always been able to do that particularly well.....and I think it is very telling.....that the NHS has not chosen to be one of the GP Systems of Choice."

NHS3: "You know I spend most of my week sitting in meetings with people saying.....who is going to pay for this.....it's a very difficult question.....I think there would probably be resistance from Trusts to pay for it.....I am sure if you pitched up at the hospital and said look we have this great system we want to implement but it would cost you.....I think they would say thank you very much but don't call us"

IT1: "Fundamentally a lot of these GPs work in the same way, and they have the same tools available to them, but to introduce an application like this, it needs to be affordable for whoever is going to fund it whether it's the PCT, the GPs, it's got to be the right price, the price is one of the biggest things."

Different funding models were explored including GP funding and the current NHS funded models with commercial CDSS suppliers including GP clinical system providers. On the whole the consensus was that either central funding from the Department of Health or an extension of current arrangements with local NHS organisations would be best suited. None of the informants supported a GP funded model. In addition the informants described the potential use of savings generated by moving transplant clinics from secondary care to primary care as possible source of funding. Key informant and suggested funding models are shown in Table 3.11.

**Table 3.11 Funding models of a CDSS to support the use specialist drugs by key informant**

<b>Key Informant</b>	<b>Central funding</b>	<b>Extension of NHS funding</b>	<b>GP funding</b>	<b>Other funding</b>
<b>GP1</b>	x	✓	x	x
<b>GP2</b>	x	✓	x	x
<b>NHS1</b>	✓	x	x	x
<b>NHS2</b>	✓	✓	x	x
<b>NHS3</b>	✓	x	x	x
<b>NHS4</b>	x	x	x	✓
<b>DS1</b>	x	✓	x	x
<b>DS2</b>	x	✓	x	x
<b>DS3</b>	✓	x	x	x
<b>DS4</b>	x	x	x	✓
<b>IT1</b>	x	✓	x	x
<b>IT2</b>	x	✓	x	x

#### **3.12.4.1 Central funding**

The views of the informants that supported central funding are shown in Box 47. Funding was described in relation to both technical and regulatory requirements that would need to be fulfilled if new systems were to be developed. In addition the costs involved in both piloting and wider roll out were described as considerable and not possible without central funding. Central funding was in reference to the Department of Health (DH), rather than from local NHS budgets that would be managed at a local level with NHS organisations such as CCGs and IT teams.

**Box 47: Key informants and views on central funding**

DS3: "So go to the DH and say you know prescribing tacrolimus needs several million pounds spent on implementing a shared care protocol to ensure the safety of patients and win that business case, and then you can do it and actually technically it is not that hard as there is already existing stuff you can pick off the shelf that would help you."

NHS1: "The real issue here then is around who potentially can fund that in the future you could be looking at the Commissioning Board, if it's a service that's in the description of those that are going to be handled in the future.....presumably there would be the patient safety focus, that would be the argument to fund it....on the flip side it might be a CCG.....I think that funding through the Commissioning Board might be more successful if the service is based in that set of commissioning requirements."

NHS2: "Whether the Government themselves given that the central spine system is not going to work would send any central funding in this direction so it might be worth trying it out."

NHS3: "So it would be getting buy in.....so more likely to be a central funding issue rather than a local funding issue and then you can say well this will improve patient safety globally and then you can turn around and say well it is going to improve patient safety locally so either the two groups have buy-in to it, or it has to be centrally funded."

**3.12.4.2 Extension of NHS funding arrangements**

The views of the informants that supported an extension of current NHS funding arrangements are shown in Box 48. The informants described this in relation to the emergence of CCGs and how different operating models could affect decision making in terms of supporting implementation, including liaison with secondary care. Both GPs supported NHS funding and utilising existing systems more effectively. The NHS IT managers described either direct CCG funding or through a GP systems supplier business case. In addition one suggestion was for emerging CCGs or groups of CCGs could take this on with agreements with local hospitals.

These local funding arrangements could be tailored and managed at a CCG level rather than a central DH model and depending on the range of stakeholders involved could lead to a number of different models that would require locally agreed management frameworks.

**Box 48: Informants and views on NHS funding arrangements**

DS1: "In the new NHS this firmly sits with the CCGs, at the CCG wallets really, and I think the multi-million dollar question is which of the CCGs is going to see this as a prescribing safety issue, big enough to tackle and you can say to the CCG we need to deal with."

DS2: "So then it can be an extension of the system the GP already has.....which depending on the exact complexity of what you want it is not going to be that expensive.....if you wanted a stand - alone system that was used by the GP for these drugs and by hospital clinicians that initiated the drug it becomes a different cost model altogether, particularly if the hospital records are still paper."

NHS2: "It might be you have to take it to individual CCGs or groups of CCGs and say this is the system.....you know would you and your user hospitals sign up to it and it might be different funding agreements in different patches."

GP2:"There is a real sense to me that this can actually can come out of the products.....implementing the products in a more intelligent kind of way."

IT1: "Yeah, I don't know what the system suppliers charge...it would be something that would be taken into account.....they will probably do a business case."

IT2: "You wouldn't get the system suppliers to do it or the GPs either; it would have to be the CCG."

**3.12.4.3 Other funding models**

The informants described alternative funding models and these are shown in Box 49. Suggestions included the possibility of a primary care based service rather than a hospital based one to support on-going care to include monitoring post transplantation. Primary care based clinics cost the NHS considerably less than secondary care clinics and were identified as a potential funding stream.

Investing in a CDSS was also described in relation to the cost of patients suffering adverse events and the cost of receiving a transplant.

**Box 49: Key informants and views on other funding models**

DS4: "What you have to look at is not just the system implementation cost but also the net savings.....or the net cost.....so if somebody falls through the net and does not have their azathioprine or any other immunosuppressant and if they reject as a result of that.....what is the net cost to the NHS, probably hundreds of thousands or millions and if the patient survives let alone the cost if he doesn't.....then you then have to look at the incidence of that complication, so actually each time he misses azathioprine it costs us a £1 million."

DS4: "A consultant appointment is £220.....but actually what I would like to see if a patient had tacrolimus that they would be given a 20 minute appointment with the GP rather than a 10 minute appointment.....and the GP would have to be able to demonstrate that everything is safety netted properly, and that should be remunerated."

NHS4: "Sure, what we are talking about is a shared effort by the primary care and secondary care sectors to move something from secondary care to the primary care sector, the cost would have to borne by the two of them together, so they would both have advantages they would both stand to benefit from it."

NHS4: "So secondary care would have a relatively straight forward but time consuming task off its hands, the primary care sector could then repatriate the appropriate funding.....the secondary care sector is relatively unlikely to stump up the money for an initiative whose purpose is to repatriate something to primary care.....so clearly secondary care needs to be involved in the advising and designing the decision tree of the decision support mechanism."

### **3.13 Discussion**

Of the primary themes safety and the use of IT systems were the predominant areas that emerged from the key informant interviews. Safety was discussed not just in terms of prescribing and the use of specialist drugs but also in the way patient care was being delivered through clinical services. IT systems within the NHS were described from both historical and current perspectives in both primary and secondary care settings although the majority of experience as expected was within primary care and general practice.

In terms of costs, financial aspects were described from a range of perspectives reflecting each stakeholder group and the roles and priorities of individual informants.

#### **3.13.1 Safety**

Aspects of safety were raised throughout the interviews either from past experiences in prescribing, monitoring arrangements, use of specialist drugs and in attitudes towards CDSS and improving current models of care. Medication safety is an area of international concern with systematic reviews estimating that 3-4% of all unplanned hospital admissions are due to preventable drug related morbidity with the majority attributed to shortcomings in the prescribing and monitoring aspects of medicine usage (Dreischulte and Guthrie 2012).

#### **3.13.2 Prescribing**

Safety in relation to prescribing was a prominent feature described in a range of experiences involving drugs used in various clinical indications. In relation to specialist drugs, the predominant aspects to safety were described from adverse experiences such as side effects and managing drug interactions. Positive aspects described by the secondary care clinicians included the use of immunosuppressant drugs in organ transplantation and how services had developed to accommodate the growing number of patients. The secondary care clinicians were all highly experienced and would clearly be comfortable in all aspects of renal medicine including the use of specialist drugs. However, in contrast both of the GPs described a range of concerns and adverse experiences in relation to prescribing specialist drugs. In the UK a systematic review of prescribing error rates in primary care identified key stages of medication management where error rates of over 50% occurred, such as repeat prescribing reviews, interface prescribing, communication and patient adherence (Garfield et al 2009).



The authors identified an overall GP prescribing error rate of 7.5% and also that only between 4% and 21% of patients received optimal benefit from their medication. In addition an estimated 1 in 15 of hospital admissions were medication related and two thirds of these were preventable with this level of risk was greater in certain patient groups such as the elderly or those receiving high risk medications.

In a recent UK based retrospective analysis of 6048 prescription items issued to 1777 patients across 15 GP practices, Avery et al (2013) reported an overall GP prescribing error rate of 4.9%. The vast majority of errors were described as of mild to moderate severity with 0.2% of prescription items having a severe error. The authors reported that prescribing a drug that required specific monitoring including the immunosuppressant drugs methotrexate and azathioprine was associated with a three-fold risk of error. Slight et al (2013) described the outcomes from a qualitative study that explored the causes of prescribing error with staff from 15 GP practices in the UK that comprised of semi-structured interviews (n = 34) and six focus groups (n = 46). Seven categories of high level error producing conditions were identified; the patient, the team, the working environment, the task, the computer system and the interface between primary and secondary care. The authors described the underlying causes of prescribing and monitoring errors as complex. Key recommendations were made in relation to GP training, continuing professional development, clinical governance, effective use of GP clinical computer systems and improving safety systems.

### **3.13.2.1 Communication**

Both the GPs and secondary care clinicians in this study described problems in this area particularly with the current paper-based system of communication. The accuracy of patient medication was a particular theme that highlighted discrepancies in record keeping between primary care and secondary care. A number of examples were given where medication was either initiated or stopped within secondary care but was not reflected in medication records held at the GP practice. The willingness to prescribe specialist drugs was a clear concern for both GPs described in experiences where communication with secondary care was either lacking or absent. Hampson et al (1996) described a range of issues from the primary care and secondary care interface with communication described as fundamental and one of the busiest areas of data transfer. Avery et al (2010b) reported that a range of adverse outcomes had been attributed to problems with communication at the interface between primary care and secondary care including medication errors.

In addition the author described problems in relation to communication included those not just between individual clinicians in primary and secondary care but also between clinicians and patients.

In a pharmacist-led review of 126 medical patients and 51 surgical patients in the North West of England, Collins et al (2004) identified a range of discrepancies in both medication and dosages prescribed within in-patient settings when comparing medical notes to drug charts and comparing discharge information to records held within primary care settings. A total of 51 medicines were identified that were not on the records of either the GP or nursing home, and these accounted for approximately 5% of all medicines recorded. The authors concluded that the study supported previous findings that there were substantial numbers of discrepancies between documented sources of patients' medicines and what patients reported what they were taking. In addition the authors reported that the inaccuracies observed with GPs' records in comparison with hospital records suggested that there was no gold standard in medication history available, other than a list of drugs taken from a patient who is perceived to be reliable and to achieve such a standard would require improved communications between healthcare professionals.

### **3.13.2.2 Clinical responsibility**

Where specialist drugs are concerned specific continuous management and clinical monitoring may be required and not all GPs will have the expertise or experience to undertake the full clinical and legal responsibility to prescribe specialist drugs (Khambh and Barnick 2007). In a UK national survey of both GPs (n = 1887) and hospital consultants (n = 729), Sibbald et al (1992) reported on the investigation of some of the problems reported at the hospital and primary care interface.

Overall, 570 (46%) GPs reported that they had been asked by a hospital to prescribe drugs where they had felt unable to take clinical responsibility. The specialist drugs reported were those used in fertility treatments, growth hormone, anticancer treatments (immunosuppressant and cytotoxic drugs), and drugs used in renal failure (fluid for continuous ambulatory peritoneal dialysis and erythropoietin). The principal reasons cited for not being able to undertake this responsibility included difficulty in detecting side effects, uncertainty about explaining treatment to patients, difficulty monitoring dosage, high cost of a drug, and a lack of knowledge about the treatment. The issue of clinical responsibility was described by the GPs and the secondary care clinicians including the use of traffic light schemes.

Overall a level of concern and anxiety was expressed by the GPs in terms of prescribing specialist drugs and undertaking clinical responsibility. Horne et al (2001) described clinical responsibility as a consistent theme and the need for both GPs and hospital doctors to agree respective responsibilities.

### **3.13.2.3 Monitoring**

Monitoring is a periodic measurement that guides the overall management of either acute or chronic illness and can be performed by clinicians, patients or both (Glasziou et al 2005). Monitoring can have a positive effect on treatment such as improving adherence, selection of appropriate medication, better titration of dose and learning about non-medical factors that may affect treatment outcomes. Managing prescribing is often finding the correct balance between therapeutic efficiency and adverse side effects of medication (Johnston and Holt 1999). The process of therapeutic drug monitoring suited a range of drugs specifically those that exhibited a narrow therapeutic index drugs where the differences between drug concentrations exerting benefit and those causing adverse effects were small. In the case of immunosuppressant drugs such as ciclosporin and tacrolimus, small variations in drug exposure can result in reduced immunosuppression or drug toxicity with potentially adverse effects on patient outcomes (Johnston 2013). Monitoring arrangements were an area of considerable concern described by both GPs in terms of on-going management of patients. The GPs described situations where there was a lack of either recent blood tests and or knowledge of what specific patient monitoring was required. There are a lack of published studies that have specifically explored patient monitoring in relation to specialist drugs, although Horne al (2001) described some of these activities such as carrying out routine checks such as blood pressure, urine analysis and taking blood samples.

### **3.13.3 Experiences of specialist drugs**

A specific area of concern was the numerous citations by the secondary care clinicians of experiences of adverse events in relation to the use of immunosuppressant drugs. These related to two key areas, drug interactions and the introduction of generic formulations of tacrolimus.

#### **3.13.3.1 Drug interactions**

Drug interactions occur when two or more drugs when taken concomitantly interact in such a way that it leads to the effectiveness or toxicity of one or more of the drugs being altered (NPC 1999).

The drugs that are likely to be involved are those with a narrow margin between the therapeutic and toxic dose, those requiring careful dosage control and those which either induce or inhibit liver enzymes. The effect and severity of drug interactions may vary considerably from one patient to another with the elderly, patients taking multiple medications and those with impaired renal or liver function most susceptible. Both the GPs and the secondary care clinicians described the importance of drug interactions from a range of experiences and perspectives. A practical difficulty described was that where prescribing was retained in secondary care the use of those drugs would not appear within the electronic health record held at the GP practice. Although manual alerts could be added to the GP held record, electronic drug interactions provided by CDSS would not be able to alert the prescriber if an interacting drug was prescribed. There are no published studies that have specifically explored this aspect of prescribing either in relation to improving CDSS and or the ways to facilitate on-going prescribing where hospitals continue to prescribe specialist drugs. The secondary care clinicians described experiences of where patients had presented to clinic having been prescribed drugs that had interacted with their immunosuppressant drugs causing either under immunosuppression and were at risk of graft rejection or over immunosuppression and were at risk of infection.

### **3.13.3.2 Generic prescribing**

In the UK generic prescribing is acknowledged as desirable and representing high quality prescribing (Duerden and Hughes 2010). The benefits of generic prescribing include including reducing the risk of error as each drug has only one international chemical name rather than many brand names and, usually, reducing the cost of prescribing. The informants described a range of adverse experiences following the introduction of generic formulations of tacrolimus and newer formulations of existing branded tacrolimus, including examples where patients had acute organ rejections and in one case a fatality. These experiences correlated well with published alerts and warnings issued in the UK and the use of tacrolimus (MHRA 2009, 2010, 2012). The secondary care clinicians described some of the difficulties in ensuring that GPs prescribed immunosuppressant drugs by specific brand despite stipulation within shared care protocols and in communications to GPs. A number of scenarios were described where formulations were inadvertently switched either when generically issued prescriptions were presented at community pharmacies for dispensing or where GPs changed prescriptions for patients between different branded formulations.

### **3.13.3.3 Repatriation**

The secondary care clinicians described in detail examples of inadvertent switching of tacrolimus formulations due to branded products not being specified on GP prescriptions resulting in adverse events including organ rejections and a fatality. In addition the secondary care clinicians described some the strategic planning and decision making that eventually initiated the repatriation of the prescribing of immunosuppressant drugs. In 2011 some UK renal transplant units began to commence new patients on Adoport® following the outcomes of a national tender for immediate release formulations of tacrolimus that resulted in significant savings to the NHS against the use of Prograf® (Devaney and Lee 2013). In addition the national tender also included oral formulations of mycophenolate however unlike tacrolimus bioequivalence problems were not an issue with this drug. Recent reforms in NHS commissioning arrangements for specialist drugs and services including organ transplantation have meant that repatriation of the prescribing of immunosuppressant drugs to secondary care is set to increase across the country (Devaney and Lee 2013).

### **3.14 Specialist drugs and shared care protocols**

A number of published studies had either evaluated or explored the development and / or use of shared care protocols in the UK (Gerada et al 1999, Duggan et al 2001, Horne et al 2001, Salt et al 2005, Lilife et al 2006, Crowe et al 2009). The attitudes and experiences of the key informants in relation to specialist drugs and shared care protocols reflected some of the reported outcomes of these studies. These experiences highlighted specific underlying issues such as poor communication; a reliance on paper based systems, time constraints and the access and availability of shared care protocols.

#### **3.14.1 Attitudes and experiences of shared care protocols**

Emerging themes reflected a mixture of both positive and negative experiences and attitudes to shared care protocols, however a key feature was the particular negativity towards their use from both GPs. Major themes that emerged from the data in relation to shared care protocols described the development process, quality, availability and acceptance by GPs. Significantly nearly all of the positive aspects around shared care protocols came from the secondary care clinicians, specifically in relation to the developmental and approval process. These included examples of how aspects of the design process could improve the quality and arrangements for monitoring.

In contrast however the views and experiences GPs did not reflect this and provided a contrasting picture particularly with regards to the quality and availability of shared care protocols. These results broadly reflected the outcomes from previously published studies in relation to specialist drugs and shared care protocols. Duggan et al (2001) reported mixed attitudes towards shared care protocols with the former health authority advisers (medical and pharmaceutical) as predominantly negative whilst hospital pharmacists as positive. Horne et al (2001) reported on the overall dissatisfaction of GPs with arrangements for prescribing specialist drugs in contrast to hospital doctors who were generally satisfied. The authors described the negative attitudes of GPs in relation shared care protocols including a lack of involvement in monitoring, a lack of experience and that protocols were not helpful as they were time consuming to develop for small numbers of patients. In terms of the key informants both GPs reported that had either personally or were aware of colleagues who had been involved in developing shared care protocols. Crowe et al (2009) described specific concerns that adversely affected the acceptance of shared care protocols including a lack of GP input into development, the authorising process, a lack of availability and the on-going monitoring and patient management.

#### **3.14.2 Developing shared care protocols and their quality**

Positive aspects to shared care protocols came from experiences around the development process described by the secondary care clinicians. The responsibility for developing, maintaining and approving shared care protocols has been described as a shared process involving stakeholder groups from both primary and secondary care such as local prescribing or medicines management committees with GP involvement (Khambh and Barnick 2007). One such example has been the development of localised shared care protocols in line with UK National Service Framework standards to improve the treatment of mental health (Snowden and Marriott 2003). Overseen by a multi-agency steering group, this six-month project drew on the results of an initial systematic literature review which were compared and contrasted by a facilitated group of primary and secondary care clinicians. The authors reported that using local clinical consensus was an effective method for adapting clinical guidelines to local circumstances. The development of shared care protocols for immunosuppressant drugs in renal transplantation was explored with the secondary care clinicians, to include the writing, management and approval process in conjunction with primary care organisations.

The process was described as pharmacist led involving a renal directorate pharmacist, formulary pharmacist and final approval by a medicines committee

where GPs attended that covered a number of primary care organisations. However both GP1 and GP2 described that they had no experience in either writing or in the development of shared care protocols. Gerada and Tighe (1999) and Duggan et al (2001) have reported on the limited role of GPs in the development and use of shared care protocols.

Despite the positive experiences described around the developmental and approval process of shared care protocols and the approval process involving PCT medicines management teams the opinions and experience of GP1 and GP2 raised doubts about whether these systems were effective in real terms with the most widely cited problem being the quality of shared care protocols. A wide number of examples were given describing specific issues such as inappropriate drug selection, written quality, variability, and the ease of use for general practice. Similar drawbacks with the quality of shared care protocols were described by Duggan et al (2001), including variability and a lack of apparent standards either within or between geographical regions.

### **3.14.3 Acceptance of shared care protocols**

GPs may often lack the relevant skills and expertise to undertake the full legal and clinical responsibility for prescribing specialist drugs; hence a shared care arrangement including an appropriate protocol will in many cases be appropriate (Khambh and Barnick 2007). Although the desired effect of introducing shared care protocols was to address this issue this was not reflected from the range of experiences described by the informants. A number of issues were cited as barriers in the acceptance of shared care protocols that provided some insight into this area such as GP workload, complexity of the arrangement and dissemination from secondary care. Ilife et al (2006) reported a similar resistance to shared care from within general practice with concerns on staffing, time constraints and a lack of experience and confidence in making and disclosing a diagnosis. The barriers to acceptance of shared care protocols described by the informants differed from those cited by Duggan et al (2001), where the main barrier was described as cost shifting. The informants described a range of issues such as clinical responsibility, role of PCTs, monitoring arrangements and GP workload.

#### **3.14.4 Awareness and availability**

Shared care protocols are widely available to download from the websites of approving bodies such as area prescribing committees (Department of Health 2012). However the actual local awareness and availability of shared care protocols was a key problem described by both GPs and the secondary care clinicians. Some of these problems highlighted specific issues such as confusion over responsibility for dissemination, use of paper based protocols and identifying updated versions. Crowe et al (2009) cited similar experiences describing the importance of distributing paper based traffic light lists at practice level and failings from a PCT perspective in the dissemination of shared care protocols and raising awareness of their existence with GPs. Access and availability of resources was a key concern for the informants despite the dissemination process now in place in terms of NHS internet and extranet access. Being unable to locate shared care protocols was a concern and coincided with issues in general regarding accessing to information within primary care. Navigating extranet sites was described as difficult even for IT literate individuals and in a busy GP consultation time constraints were also considered having an adverse effect on access.

#### **3.15 Information technology: Systems and functionality**

The informants described the use of computers and IT systems within general practice from both an end user perspective i.e. GPs and practice staff and from a technical perspective in terms of functionality including key aspects of management and regulation. Overall in terms of usage a mixed picture was portrayed of computerised systems and acceptance of new technologies. Computers were described as essential in the running of general practices such as in offering appointments, processing patient data, pathology links with hospitals, generating prescriptions and alert and reminder systems. A specific aspect was the wide range of both clinical and practice administration functionality that was available for use in terms of applications provided by the GP clinical system providers and external software applications. Internet availability provided access to major resources for general practices in terms of communication and operational links to applications such as NHS mail, Choose and Book local NHS extranet websites. In terms of prescribing support computer usage was described as essential in terms of managing health records and medication to include the availability of CDSS. However a number of problematic aspects of computer use were described by the informants including issues in relation to practice workload, computer maintenance, and training requirements for staff.



In addition specifically for the GPs a clear problem was time constraints in terms of overall computer use including additional software applications during consultations. The informants also described specific problems in terms of changes to computers and software applications and the impact to general practices and in particular to end users. Even small changes could potentially impact on general practice workload and were described in terms of the way new software applications were implemented. The acceptance and use of new technologies was described as variable with key enablers described as the provision of adequate training, targeting slow adopters and better use of peer support.

The overall experiences of the informants correlated with published studies that have evaluated computer usage within general practice. An early systematic review of 30 published evaluations from the UK and abroad Sullivan and Mitchell (1995) reported that although computer use during GP consultations had helped improve clinician performance the length of patient consultations had increased. The authors later repeated this systematic review identifying 61 studies that examined the effects of computers on clinician performance, patient outcomes and the attitudes of both clinicians and patients (Mitchell and Sullivan 2001). The authors reported mixed experiences of usage with computers in primary care, with use reported to increase consultation time and whilst reminder systems benefited preventive tasks and disease management these improvements were lost when reminders were stopped. In addition the authors described other concerns such as the impact on privacy, the doctor / patient relationships, cost, time and training requirements. In contrast positive experiences included generating prescriptions, increasing generic prescribing and managing investigations and tests. Morris et al (2003) reported from a national survey of all Scottish GP practices, that most GPs made frequent use of computers for a variety of clinical and practice management activities however other staff wishing to make a greater use of computers was unable to due to a lack of access.

In a broader study involving London based GPs, practice staff and PCT management, Mannan et al (2006) reported that although general practices acknowledged the benefits of new technology concerns remained around acceptance due to issues such as the mistrust of technology and fears with the increased workload levels required. In addition the authors recommended that IT implementation teams should focus their attention to those practices that have been reluctant to use technology to support both clinical care and practice management.

More recent studies have explored computer usage during consultation by use of video recording techniques. Chan et al (2007) reviewed 100 patient consultations involving 10 GPs and reported on three types users of computers, as either minimal, continuous or end users, where end users would only use the computer at the end of the consultation. In a broader examination Kumarapeli and De Lusignan (2013) used multichannel video to record 163 patient consultations with 16 GPs based in 11 practices and described usage in relation to proportion time spent on the computer but also described 34 different tasks commonly performed classed as either continuous, episodic and singleton (one off). In addition the authors reported on a range of factors that affected patient interaction including having to multitask, interruptions and room layout.

### **3.15.1 Data quality and read coding**

Computerisation has introduced electronically accessible information supporting both clinical and non-clinical practice management. A key aspect has been the ability to electronically record patient specific information to an individual health record and the ability to recall or retrieve aspects of patient or clinical relevant data. Lawrenson et al (1999) has reported on the development of three major national databases developed to routinely collect specific data from selected general practices in the UK; the Department of Health owned General Practice Research Database (GPRD), and two commercially owned databases, Mediplus and the Doctors Independent Network Database (DIN). Key to these national databases is the quality and accuracy of data that is recorded by use of standardised systems of coding. A specific problem and area of concern described by the informants was the process of managing paper based information and specifically ensuring relevant data was electronically recorded and coded. In addition inaccuracies were cited as a key area that had a significant effect on both clinicians and patients. This was described particularly between the primary care and secondary care interface where patient specific information was reported as often either missing or lacking. A recurrent theme was the accuracy of medication lists held by GPs compared to those held in secondary care.

De Lusignan (2005) has described coding as a complex task and suggested that in order to overcome difficulties clinician attitude and IT aptitude be addressed in addition to identify and technical barriers or organisational factors. Described by the authors as the first systematic review to investigate the measurement of the quality of general practice held data Thiru et al (2003) identified 47 studies from the literature of which 31 were from the UK.

However due to a lack of standardised methods for the assessment of data quality in electronic patient records the authors were unable to compare results between these studies. The authors reported that limitations in data quality would remain when systems allowing the opportunity to record clinical data in different forms i.e. both paper and electronically continued and that the validity and quality of electronically held data would improve as clinicians migrated to electronic systems.

For clinicians having electronically available data has huge advantages in that clinical and management decisions can be quickly and safely made without the need to manually check for information. GP system suppliers are required through contractual agreements with the Department of Health and the GPSOC program to provide computer systems that meet specific specifications including CDSS to provide drug related safety information such interactions and warnings. However reports have highlighted safety deficiencies within GP computer systems where warnings failed to alert end users when expected (Fernando et al 2004). In addition the need for improvement strategies for GP clinical system suppliers have been recommended to include human ergonomics in the design of hazard alerts (Avery et al 2005, 2007). Being able to trust data being presented electronically was a key area for the end users particularly the GPs and thus support the use of IT systems in general practice including CDSS for both prescribing general practice management. The informants highlighted specific key processes around maintaining the quality and robustness of electronic data and in terms of on-going development of products. In addition the informants provided a range of examples where inaccurate coding of patient data or the perceived irrelevance of prompts and alerts such as with drug interactions led to a distrust of the functionality and the subsequent over-riding of alerts.

### **3.15.2 Accreditation**

A key aspect in relation to standards was the concept of accreditation of software systems in particular with reference to CDSS. Introduced in 1993, Requirements for Accreditation (RFA) ensured that GP clinical systems provided agreed core functionality and conformed to national standards to include the provision of CDSS (Sugden et al 2008). In addition the Department of Health recommended that health authorities should only reimburse GP practices expenditure in respect of GP clinical systems if the expenditure related to a system that was accredited to RFA standards.

In order to support GP practices move to systems that were compliant with the introduction of the single electronic care record and NHS spine, the RFA was replaced by the GP System of Choice (GPSOC) initiative which encouraged GP clinical system providers to upgrade their systems through a series of compliance levels in order to achieve a greater level of standards (Sugden et al 2008). However although GP clinical system suppliers were required to meet these regulatory standards a specific issue that the informants described was the historic lack of regulatory standards in relation to CDSS.

The CDSS informants described recent developments in order to bridge this gap with software accreditation. The accreditation of any system confers a degree of quality assurance. In the UK the NICE Accreditation Programme recognises organisations that demonstrate high standards in producing health or social care guidance with users of accredited guidance can therefore have high confidence in the quality of the information (NICE 2013). Organisations may publicly display a seal of approval called an Accreditation Mark for 5 years after their processes have been accredited. The informants described the accreditation for a specific CDSS that provided prescribing support within GP clinical systems. However it emerged that the accreditation only covered the authoring process behind the product and not the actual clinical content. In addition the informants also described mixed attitudes to a recent European Directive that stipulated that CDSS were stand-alone software that were to be classified as a medical device (EMA 2012). The implications for suppliers were described as particularly difficult as the MHRA in UK would have to ensure adherence to the European Directive. The informants described the considerable investment in terms of time and money in order to meet the requirements of the Directive and the financial penalties for not doing so. In addition this would have a specific impact for the introduction of any new CDSS in that the product would need to meet the requirements of the Directive.

### **3.15.3 The views and experiences of CDSS in primary care**

The informants described key positive aspects to CDSS specifically in relation to the active alert process. Benefits cited included cost saving alerts such as those provided by Script-Switch, drug safety alerts such as drug interactions the on - going alerts and reminders provided within GP systems to support QOF. In addition CDSS was described as supportive around the prescribing process such as repeat prescribing in both passive and active formats and allowing engagement with patients during consultation.

Quality was as a key feature exemplified through robust data checking and authoring processes from providers of CDSS and developments such accreditation. In contrast some of the problems associated with CDSS were described in relation to a lack of integration with GP clinical systems, the implementation process particularly with the effects on GP practices such as staff training and having to deal with technical difficulties. In relation to IT systems and initiatives that were being introduced by NHS Connecting for Health Mannan et al (2006) reported that the majority of practice staff expressed concerns with these initiatives such as workload pressures, a lack of training and costs of implementation. In addition practice staff expressed fears that change would be forced onto them.

A specific theme that the informants described was the need to override alerts provided by CDSS particularly during patient consultations with time being a significant factor. Similar findings have been reported from studies that have explored attitudes and perceptions of CDSS with GPs. Magnus et al (2002) reported that 22% of GPs surveyed (n = 220) admitted to frequently or very frequently overriding drug interaction alerts without proper checking with possible reasons cited as the perception that the alerts were frequently irrelevant. (Rosseau et al 2003) reported three main areas of concern with CDSS amongst GPs and nurses (n = 40) included the timing of the alert, ease of use of the system, and helpfulness of the content. Short et al (2004) reported on practical barriers to the use of CDSS during consultations including limitations of practitioners' IT skills, a lack of understanding of the risk output of systems, concerns about communicating risk sufficiently well to patients and time constraints.

A particular theme that emerged was the relationship between commercial system suppliers, NHS IT management and the end users of systems including CDSS. In terms of CDSS, Delaney et al (1999) reported that despite the huge potential in its use, the concept had largely failed due to the failure to examine the needs of practitioners more closely. A number of examples were provided where engagement with end users was described in specific detail highlighting problems in the development, use of and implementation of either new or changes in IT systems including CDSS. The CDSS informants in particular described the importance of engagement with the end users and how user groups played a pivotal role in maintaining and developing products and services.

### **3.16 The views and experiences of CDSS in secondary care**

Although limited compared to primary care, the informants described experiences of CDSS in secondary care. Groundrey-Smith (2006) has reported on the limited experience of electronic prescribing within UK hospitals and the small number of studies that have cited observed benefits including the availability of CDSS as a support tool at the point of prescribing. Although none of the secondary care clinicians currently used electronic prescribing systems within secondary care there was a general awareness and acceptance of its benefits including the use of CDSS. A number of references were made to either the imminent or planned implementation of electronic prescribing systems within hospitals. A number of examples of CDSS were described as either being used or developed locally within specific clinical units independently of secondary care information technology systems.

The secondary care clinicians described the establishment of a national network of electronic renal databases that were used to collect biochemical and haematological information to inform the UK renal registry. These experiences correlate with a recent survey of NHS hospitals (n = 101) that has shown that the uptake of electronic prescribing within UK hospitals is beginning to rise, with 70 (69%) having at least one form of electronic prescribing in use (Ahmed et al 2013). More than half (39;56%) of hospitals with electronic prescribing had more than one system in use, representing 60 different systems with the most common used only for discharge prescribing, used in 48 (48%) and specialist chemotherapy used in 34 (34%) of respondent hospitals. In addition the functionality of CDSS available was reported as being widely varied. In 2013 NHS England launched a £260 million technology fund available to NHS providers to support a move from paper-based systems for patient notes and prescriptions to integrated electronic care records and the development of e-prescribing and e-referral systems (NHS England 2013).

### **3.17 Developments and improving CDSS**

A wide range of both current or proposed developments and improvements in CDSS were explored with the informants. For general practice key areas were described in the way electronic systems including CDSS could potentially support the management of long term conditions. The current GP contract is supported by the QMAS electronic alerting system that provides financial incentives and information technology through computerised prompts and decision support to achieve evidence based quality targets (Gillam and Steele 2013). Some of the positive experiences described by the informants were of how QOF alerts had improved general practice.

One of the informants described the functionality of a primary care based CDSS that operated in the USA whereby aspects to a patient's medical care could be prioritised unlike the current QOF alerting systems in the UK. This this could be a significant area for development as more urgent interventions could be prioritised over less important ones especially if patients have limited GP appointment times. Other potentially significant areas for CDSS development included linking GP clinical systems with community pharmacies and in the on-going development and implementation of electronic prescribing systems within secondary care.

### **3.18 CDSS and specialist drugs**

Overall the concept was welcomed by all of the 12 informants. Key enablers that were described included data quality and functionality (9), joint development and implementation (8), for the CDSS to have an active alerting functionality within an electronic patient record (6) and to make use of existing systems and frameworks (5). Key barriers that were described included addressing the needs of end users (6), security and regulation (5). Of the funding models explored, the majority of the informants (7) suggested an extension of the current NHS funded model. Four of the informants suggested central funding whilst none suggested that GPs should provide funding. One of the informants described a potential funding model whereby shifting transplant clinics into primary care could release funds that could be invested into the development of a CDSS. A key aspect that emerged was the role of GP clinical system suppliers as a point of entry for the development of a CDSS to support the use of immunosuppressant drugs. Making use of existing systems and frameworks related to both financial and regulatory perspectives. The cost of developing a new product was estimated by the informants to run into millions of pounds. Without central funding from the Department of Health the only considered option would be to extend current NHS funding streams in collaboration with a GP clinical system supplier particularly with the national trend in moving general practices to hosted systems.

### **3.19 Costs**

The importance of costs were a specific feature in three key areas; drug costs, IT costs and service costs.

#### **3.19.1 Drug expenditure**

The informants provided a mixture of views regarding whether drug costs played a significant role in GP decision making in whether to undertake the prescribing of

specialist drugs. Safety related issues such as patient monitoring and clinical responsibility were described as the predominant factors. It was clear however that some of the adverse experiences associated with tacrolimus were linked to primary care drug costs and GPs having to manage indicative practice budgets. With clinical commissioning groups (CCGs) now responsible for managing primary care prescribing budgets, key decision making around commissioning of health services rests with GPs. With the drive to bring hospital services out into the community, this raises the prospect of a greater level of specialist drugs being prescribed within primary care adding additional pressures on primary care prescribing expenditure. Cost shifting from secondary care to primary care was a major issue in the 1990s with GP fundholding particularly with high cost specialist drugs such as erythropoietin in renal medicine (Stephens 2005). Significantly drug cost was not cited as a barrier by any of the informants. GP fundholding was abolished in 1997 and replaced with prescribing incentive schemes, which were designed to encourage quality improvements and cost containment in prescribing (Stephens 2005).

### **3.19.2 Funding of IT systems and CDSS**

The informants described funding arrangements for general practice and IT systems, including CDSS from both a historical perspective and in relation to recent NHS reforms. A specific aspect was the role of the NHS in terms of funding IT for GP practice in its entirety. The NHS has historically subsidised the cost of GP computer systems since the 1990s, initially through facilitation payments to improve standards e.g. immunisation and cervical cytology targets and more recently to meet the data requirements for QOF and the GMS contract introduced in 2004 (Roland et al 2012). In terms of funding arrangements the NHS provides this through the GP Systems of Choice (GPSOC) framework. Launched in 2014, "Securing Excellence in GP IT Services" announced changes in the operating arrangements including financial procedures and associated controls with regards to IT for general practice (NHS England 2014). These changes included arrangements for governance, leadership and clinical safety assurances including the availability of secure e-mail (NHSmail) for all primary care contractors. The document also outlined key responsibilities for IT infrastructure that were to be retained centrally and those for local development. A recurrent theme that emerged from the key informant interviews was the need for funding for either existing systems or any future developments in IT to be met by the NHS or by central Government and not by GP practices. In addition this also extended to additional costs to support implementation such technical support and staff training.



### **3.19.3 Commissioning of specialist services**

Important features to the development of renal units were the growing numbers of patients receiving transplants and the close affiliation of patients to transplant centres. Transplantation was described as a positive intervention both in terms of outcomes and quality of life but also cost to the NHS. The annual cost of dialysis is £30,800 per year compared to the one off cost of a transplant of £17,000 and annual drug costs of £5,000 (Johnston 2011). Costs, including drug costs although not the predominant factor were a key feature for driving forward the repatriation of prescribing and the supply of immunosuppressant drugs through homecare. Attitudes to using homecare providers to supply immunosuppressant drugs in renal transplant patients were generally positive particularly from an operational perspective by the secondary care clinicians interviewed in this study. Although financial savings were described as considerable, particularly once patients were repatriated and converted to cost effective generic formulations of immunosuppressant drugs, the safety and clinical care of patients was considered just as important.

The treatment at home of patients requiring specialist drugs and treatments such as intravenous therapies including chemotherapy and total parenteral nutrition is accepted as a safe and effective means of healthcare provision (Short and Norwood 2003). In the UK the high-tech homecare model of delivery has evolved significantly and is regulated by the National Homecare Medicines Committee (NHMC). It was recognised that market expansion in homecare required effective management to ensure patient safety and clinical effectiveness (Commercial Medicines Unit 2010). In 2011 the Department of Health commissioned the report “Homecare Medicines – Towards a Vision for the Future” (Department of Health 2011). The report made a list of recommendations to improve the financial and clinical governance arrangements for patients receiving medicines from Homecare providers. The secondary care clinicians described their experiences in some of the strategic decision making in relation to repatriation of the prescribing of immunosuppressant drugs and the use of homecare services. In 2010 the Government White Paper “Equity and excellence: Liberating the NHS” outlined key strategic steps in order to achieve financial targets to include Quality, Innovation, Productivity and Prevention (QIPP), a national program of work streams that included medicines use and procurement (Department of Health 2009). In terms of renal transplantation, this led to the development of a national “Kidney Care QIPP Plan”, which was incorporated into the strategic commissioning plans for renal care (NHS Specialised Commissioning Transition 2012).

A key opportunity identified was the wider use of generic formulations of tacrolimus which formed the basis for a national tender in 2011. Transplant centres in the UK soon introduced supervised switch programmes in order to move patients to cost effective branded generic formulations of tacrolimus (Devaney and Lee 2013). The secondary care clinicians described the use of homecare services as leverage in order to ensure patients were reviewed and appropriately managed before being transferred over to these providers.

From 2013 changes to the commissioning arrangements for specialist drugs in England have provided the opportunity for hospitals to further extend the process of repatriation of prescribing of immunosuppressant drugs (Devaney and Lee 2013). With the continued emphasis on managing expenditure in the NHS and a push towards moving secondary care services out into primary care, closer to patients NHS commissioners may see other specialist drugs as suitable for consideration for wider use in primary care such as in GP practices or community clinics supported by the provision of homecare services (Anon 2012).

### **3.20 Limitations**

The number of participants that took part was small with only two GPs that were purposively recruited to this study, both of whom were younger and very familiar with computers and IT systems. This may have introduced a level of bias towards attitudes to IT and CDSS. However as two of the CDSS informants were also practicing GPs this did allow for further data to be gathered from a clinicians' perspective. In addition only two NHS IT managers were purposively recruited to the study.

### **3.21 Further work**

In principle all of the key informants expressed positive attitudes to the concept of developing a CDSS to support the use of specialist drugs. A number of disadvantages to the current paper based systems of communication including the use of shared care protocols between secondary care and primary care were described with the predominant factor being safety. A number of operating models were suggested however key to which model would best support clinicians would depend on whether the repatriation of immunosuppressant drugs is extended to cover other forms of organ transplantation services e.g. liver and or other specialist drugs.

The secondary care clinicians described the repatriation project in terms of renal units as a pan-London initiative and with other areas of the country following suit. If prescribing is retained in secondary care an additional factor is the extent to which electronic prescribing as a whole develops within secondary care. If a hospital Trust embarks on a whole system implementation that incorporates all clinical sites, wards including pharmacy this may impact on the implementation process and a different approach may be required compared to a ward based or clinical unit based system.

Ahmed et al (2013) reported on the increasing numbers of electronic prescribing systems in secondary care in the UK but also added that many hospitals used more than one system and that there was wide variability in the functionality of available CDSS. In addition the integration with current GP clinical systems will remain a concern as the informants described a range of problems at the primary and secondary care interface such as inaccuracies in health records including medication lists. Developing existing renal databases managed within secondary care to allow electronic prescribing is potential area which could be explored, although the integration with the GP clinical system would remain key factor. In addition if a homecare model is to be the continued system of supply of specialist drugs then the integration with the homecare pharmacy computerised system could be a potential area for further investigation.

A primary care based model was suggested as a potential model by the informants either GP led or specialist led. Current GP clinical systems would be the point of entry in order for a CDSS to be developed and potentially introduced to support clinicians. The informants described a current model where all GP practices within a locality were considering moving to a single GP clinical system supplier. Two suppliers have developed clinical systems that allow multi-user access, SystemOne and EMIS Web. These are both hosted systems and allow external user access to a single record clinical electronic patient record. Potentially these systems could be introduced within other primary care or secondary care based clinics with controls over user access.

### **3.22 Conclusions**

The results of this study have shown that little has changed in terms of the views and perceptions of clinicians towards the use of specialist drugs and shared care protocols in relation to previously published literature. Khambh and Barnick (2007) suggested that proposed developments in electronic prescribing within secondary care could improve the situation with paper based systems particularly with the problems associated with communication between secondary care and primary care. The authors also highlighted that electronic prescribing systems would require significant time to become fully established before benefits would be seen. The direction of a primary care driven NHS does not appear to be changing, and the increasing trend to see a greater range of specialist drugs used within community settings either through homecare services or the introduction of other service models will continue.

The informants in this study described enablers and barriers to the development of a CDSS to support the use of specialist drugs. Six of the 12 informants described a failure to address the needs of end users as a barrier. Coiera et al (2006) reported that the effectiveness of CDDS should not be judged on performance of the software but a better understanding of cognitive and socio-technical interaction in its design. Horskey et al (2012) described poor usability as one of the core barriers to the adoption of CDSS. In addition the authors suggest that designers of systems needed to adopt methods that included user-centred, iterative design and common standards based on human and computer interactive research methods.

The key informants described a number of operating models for a potential CDSS to support GPs in the use of specialist drugs. In order to understand the actual needs of GPs as end users of a potential CDSS a specific additional area was identified for further investigation. The following chapter adopts methods used within the field of human factors and ergonomics. The purpose of this additional study was to understand from a GP perspective from real time scenarios the actual level and use of computers and software applications including CDSS at the point of prescribing both during and outside of patient consultations. In addition weaknesses or failings in existing systems could be identified and be used in the further development of a CDSS to support the use of specialist drugs.

## **Chapter 4**

# **A task analysis of the use of computers and computing software by GPs**

#### **4.1 Human factors and ergonomics**

Human factors and ergonomics apply the knowledge of human abilities and limitations to the design of systems with the goal of ensuring that the interaction between people and elements of systems enhance safety, performance, and satisfaction (Shaver and Braun 2008). Many of the advances in ergonomics originated from the needs of the military during both World Wars such as having to train pilots to operate and fly newer combat aircraft. Over the years other industries have benefited by closely examining and analysing the way humans interact with systems including motor, power and telecommunications. The UK National Patient Safety Agency (NPSA) reviewed safety critical industries such as the nuclear, rail, underground, aviation and air traffic control and identified a set of design principles that could be used to identify and evaluate hazards within healthcare settings (NPSA 2010). This report identified key human factors techniques that could support stakeholders involved in the planning, design and development of healthcare facilities, such as human error identification, hazard and operability studies and task analysis.

Task analysis has been described as a fundamental methodology that can be used to both assess and reduce sources of human error (Embrey 2000). Task analysis can be used to eliminate preconditions that give rise to errors and to support the design of new or to modify existing systems. The methods used can broadly be described either as action based approaches or cognitive approaches. Action based approaches examine systems from an operational perspective, whereas cognitive approaches examine the mental processes behind aspects to behaviour such as decision making and problem solving (Embrey 2000). Hierarchical task analysis is a systemic way of describing how work is organised and involves a top-down approach to identify the goal of a task and the various sub-tasks that need to be carried out in order for the goal to be achieved (Embrey 2000). This approach has been used for a range of applications such as interface design and evaluation, job aid design, workload assessment and error prediction (Stanton 2006). Cognitive task analysis yields information about the knowledge thought processes that impact on observable task performance (Chipman et al 2000). In addition cognitive task analysis focuses on describing the cognitive elements around decision making and judgements required in completing tasks such as situation assessment strategies and identifying critical cues and perceptual distinctions (Militello and Hutton 1998).

Hierarchical task analysis provides a method of examining work by describing human activity in the context of understanding the purpose of work in terms of the organisations and systems in which it is being carried out (Shepherd 2001). In hierarchical task analysis individual tasks are represented in terms of hierarchies of goals and sub-goals based on the concept of plans to show when a sub-goal is to be conducted and can be represented either diagrammatically or in a tabular format.

Despite the huge potential of CDSS, Delaney et al (1999) attributed difficulties in uptake was largely due to the inability to examine the needs of practitioners more closely. Coiera et al (2006) reported that the effectiveness of CDSS should not be have been judged on performance but a better understanding of cognitive and socio-technical interaction in its design. In terms of electronic prescribing, the need to present complex information in a straightforward and timely manner makes interface design critical in order to provide a balance between the completeness of data capture during the prescribing process and the ease of use for the end-user (Groundrey-Smith 2008).

In the current study the 12 key informants (see chapter 3.81), all described their views and attitudes to a proposed CDSS to support the use of specialist drugs within general practice. The key informants all identified both enablers and barriers to the concept. Key enablers described included data quality and functionality (9), joint development and implementation (8), for the CDSS to have an active alerting functionality within an electronic patient record (6) and to make use of existing systems and frameworks (5). Key barriers described included addressing the needs of end users (6), security and regulation (5). Six of the key informants identified a key barrier to implementation as addressing the needs of the end user; in this case GPs.

In a literature review of CDSS and prescribing, Horskey et al (2012) focussed on identifying best practices for clinical interventions and described poor usability as one of the primary barriers to the adoption of CDSS and a deterrent to routine use. In addition the authors identified a range of design recommendations and characteristics for CDSS in supporting electronic prescribing. These included the active or passive functionality, display features, filtering of frequent interruption and prompting for continuous maintenance of the electronic patient record.

#### **4.1.1 Error analysis techniques**

Lane et al (2006) reported on the use of hierarchical task analysis to model the drug administration process within a UK hospital. The tasks presented were subdivided into additional levels of component tasks that identified a detailed description of how drugs were being administered to patients. In addition the authors applied an error analysis technique based on the systematic human error reduction and prediction approach (SHERPA). This technique identifies and classifies errors that can occur and at which points during each task at which they may occur. Based on the output of the SHERPA analysis the authors were able to suggest design solutions to mitigate the errors in the drug administration process. A wide range of predictive error analysis techniques have been developed by different individuals from within different industries. However most of these are commercial in origin not subjected to formal validation and are rarely published in the academic literature (Lyons et al 2004). In an early evaluation Kirwan (1992) compared SHERPA with eleven other error analysis techniques based on a number of criteria including accuracy, comprehensiveness, usefulness and the ability to see if the incidents predicted by each model matched those that had actually occurred. The author reported that SHERPA was the most highly rated by expert users. In a later revised wider evaluation of 38 techniques, Kirwan (1998) suggested that no single technique was optimal based on all of the qualitative criteria used. In addition the author described that few techniques were highly structured thus only aiding the assessor rather than being fully prescriptive. Whilst healthcare has increased the awareness of retrospective safety assessment techniques, such as root cause analysis, adoption of predictive safety assessment techniques has been slow due to the lack of support in technique choice and practical knowledge in the published literature (Lyons 2009).

Examples from the UK within healthcare settings where a predictive model such as SHERPA has been used or adapted include the use of anaesthesia (Phipps et al 2008) and during endoscopic surgery (Joice et al 1998). Phipps et al (2008) reported on the results from a hierarchical task analysis from the start of a preoperative visit to the postoperative handover of patients to recovery staff. This identified the type of behaviours involved according to the phase of anaesthesia. The SHERPA analysis used in this study identified that errors during preoperative planning and perioperative maintenance could have been avoided by the use of measures to support information handling and decision making.



In addition errors during machine checking, induction and emergence could have been reduced by streamlining or automating task steps, or by making changes to the physical design of the work environment. In an observational study of laparoscopic cholecystectomy, Joice et al (1998) described how an error analysis model adapted from the SHERPA model was used to identify aspects of the design and use of instruments and surgical training. In addition the study identified the differences between tasks performed that required further evaluation in order to identify performance related factors and so reduce error rates.

#### **4.1.2 Activity diagrams**

Activity diagrams display a sequence of actions including alternative paths that can be followed. These are often organised as swim lanes in order to identify who or what is responsible for a specific task or activity (Benson 2010). Activity diagrams have been used to model aspects of prescribing and clinician workload. In order to facilitate the implementation of electronic prescribing systems Johnson and Fitzhenry (2006) described the development of activity diagrams to model workflow patterns involved in prescription writing both during and outside of patient clinics within primary care settings in the USA. Bell et al (2004) identified distinct functionalities in relation to electronic prescribing systems available in the USA. A functional model of medication management based around the major activities of prescribing, transmitting prescriptions, dispensing, administering medication and monitoring the effects was subsequently developed.

#### **4.2 Aims and objectives**

The results from the key informant interviews in the current study identified key operational functions and characteristics of a potential CDSS to support the prescribing and use of immunosuppressant drugs to include enablers and barriers to implementation. However in order to support the operational design of a CDSS a closer understanding of the way GPs actually worked and used computers was identified as a specific aspect that required further examination. One method of supporting this process further was by observing and detailing the way GPs interact with computers and computing software. Task analysis can be used to eliminate some of the preconditions that can give rise to errors and to support the design of new or modification of existing systems.

The aim of this study to identify an operating model for a potential CDSS to support GPs in the use of specialist drugs in order to ensure high level safety and quality in prescribing, with following objectives:

- To determine the actual level and use of computers and software applications including CDSS at the point of prescribing both during and outside of patient consultations by GPs
- To identify potential weakness or failings in existing systems that could be identified and be used in the development of a CDSS to support the use of specialist drugs.

### **4.3 Methods**

The purpose of this study was to identify the way GPs actually utilise computers including CDSS both during and outside of patient consultation, and to assess risks and weaknesses in current systems. Hierarchical task analysis was chosen as the method because it specifically identifies observable actions to include any functional requirements. This is unlike cognitive task analysis where techniques attempt to address underlying mental processes that can give rise to errors which is particularly important in areas such diagnosis or problem solving (Embrey 2000). Data from the interviews and observations was initially used to develop an activity diagram that represented the way the GPs conducted their work and used their computers both during and outside of patient consultation. A hierarchical task analysis was completed specifically on the process of how GPs currently prescribed specialist drugs. An error analysis based on SHERPA was then applied to the steps involved in prescribing specialist drugs.

#### **4.3.1 Interview schedule**

An interview schedule was prepared by the research team to include specific pre-determined questions in order to collate information about the individual GP, such as experience, specialities and knowledge and use of CDSS (see Appendix 4.1). Further questions were in relation to computer use including CDSS both during and outside of patient consultation. The interview schedule was used as a topic guide and emerging themes were used to formulate further questions during each interview and observations. Each GP was asked to demonstrate how the computer and any additional software including CDSS were used either during or outside consultation to include prescribing medication.

Case scenarios were discussed with each GP to include where patients either presented with or hospitals requested prescriptions for immunosuppressant drugs. In addition these scenarios were discussed where shared care protocols were not available to the GP. These case scenarios were developed from results of the interviews with the 12 key informants (see chapter 3). Written notes were taken throughout each interview including relevant observations. These were all later checked by the researcher for accuracy.

#### **4.3.2 Selection criteria**

In total nine GPs were purposively selected, with two having participated in the key informant interviews (GP1 and GP2). A third GP (GP3) was involved in the piloting phase of the key informant interviews. Each GP was sent a participant information leaflet (Appendix 4.2), a consent form (Appendix 4.3). Interviews were arranged and conducted within each of the GPs' consultation rooms. Three GPs were each selected on the basis that they were each users of the three major GP clinical system suppliers in the UK EMIS, Vision and SystmOne. A development within this field of primary care that was identified during the key informant interviews (see chapter 3) was the national drive for GP clinical system suppliers to move over to so-called hosted systems. Benefits from the use of hosted systems include data recovery, system management, technical support, integration with other sites and access for NHS staff working from multiple locations (Barr 2008). SystmOne is a provider of a single hosted system whilst EMIS provides existing traditional GP site based systems (EMIS LV, hosted systems EMIS PCS and EMIS Web). Vision currently provides only a GP site based system. All of the GPs that were approached agreed to participate in the study.

#### **4.4 Ethical Approval**

A modification for ethical approval for the key informant interviews (Reference BDM/11/12-82) for this study was granted by Kings College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee on 9<sup>th</sup> May 2014.

#### **4.5 Results**

In total 9 GPs participated in this observational study and a summary of their demographic profile is shown in Table 4.1. Each interview lasted no longer than 40 minutes. Six of the GPs were partners at the practices they worked at whilst three were salaried GPs. The GPs qualified between 2001 and 2013. All of the GPs described themselves as having either a medium or high IT aptitude both in general and in the use of the GP clinical system within their practice. The GPs all described having additional interests and specialities. In addition one GP explained they worked at a practice accredited as being suitable for the training of doctors to become GPs.

Table 4.1 Demographic characteristics of participating GPs

Demographic characteristics	GP1	GP2	GP3	GP4	GP5	GP6	GP7	GP8	GP9
<b>Number of years qualified</b>									
< 5 years	✓								
5 – 10 years		✓		✓	✓		✓		✓
>10 years			✓			✓		✓	
<b>Employment Status</b>									
Salaried GP	✓		✓						✓
Partner		✓		✓		✓	✓	✓	
<b>Specialty</b>									
Mental Health		✓							
Musculoskeletal		✓							
Diabetes			✓						✓
Minor surgery				✓		✓			
Paediatrics				✓					
Obstetrics							✓		
Cardiology					✓				
Internal medicine					✓				
Occupational Health	✓								
Anticoagulation			✓					✓	

Table 4.1 Demographic characteristics of participating GPs cont.

Demographic characteristics cont.	GP1	GP2	GP3	GP4	GP5	GP6	GP7	GP8	GP9
<b>GP Clinical System Used</b>									
SystemOne	✓	✓	✓						
Vision						✓		✓	✓
EMIS Web					✓		✓		
EMIS LV				✓					
<b>Reported aptitude towards IT</b>									
High	✓	✓	✓					✓	✓
Medium				✓	✓	✓	✓		
Low									
<b>Reported aptitude towards use of GP clinical system</b>									
High	✓	✓	✓		✓			✓	✓
Medium				✓		✓	✓		
Low									

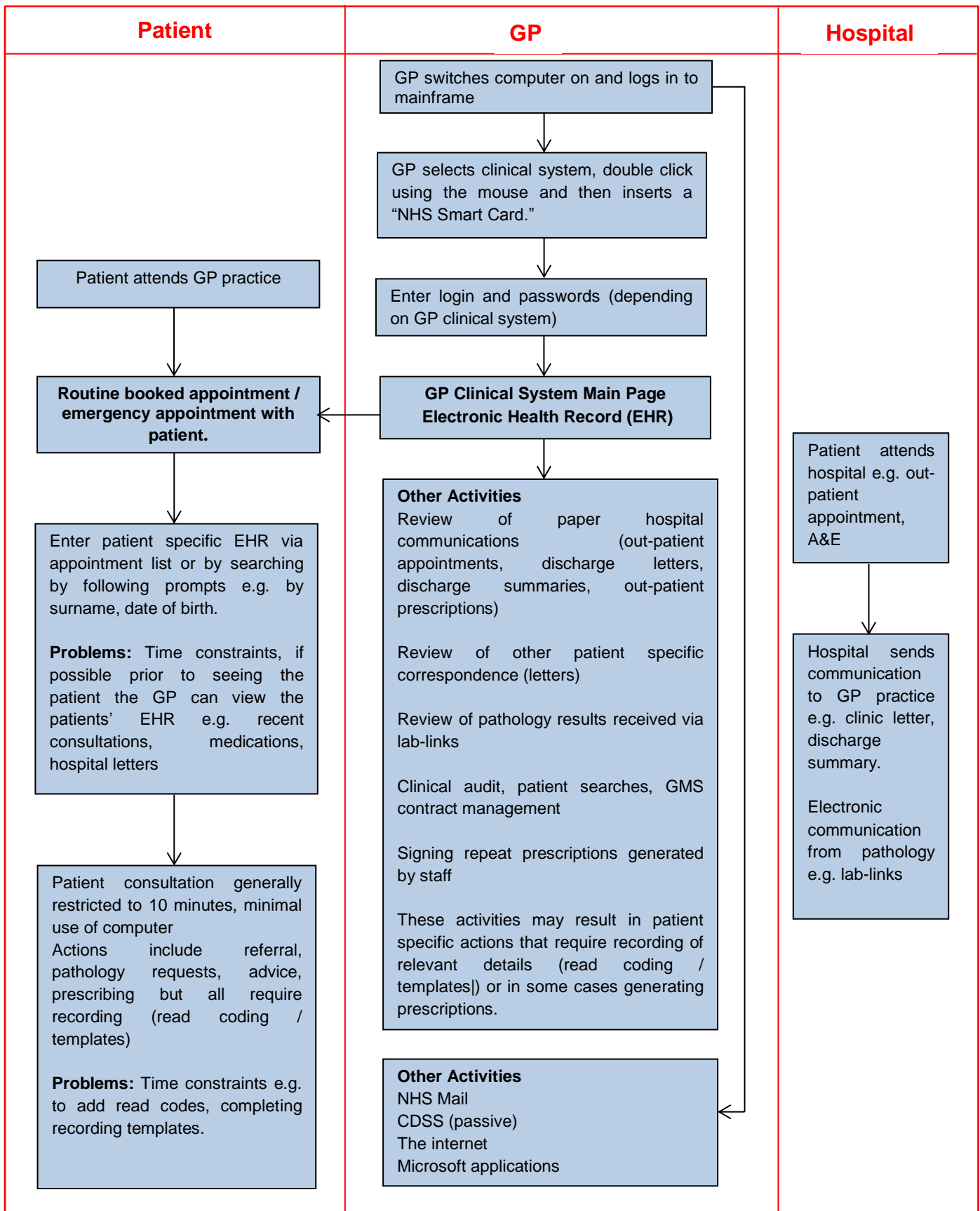
#### **4.5.1 Consultation rooms**

The GPs all worked in spacious rooms which were well-equipped and all had a desk and sat facing their desktop computer terminals. Printers linked to each computer terminal were also based on each desk. Both GP2 and GP5 had two monitors linked to their desktop computers that sat next to each other which allowed them to view the GP clinical system on one screen and other documents and software applications on the other screen at the same time. GP2 described aspects to a local IT project that provided funding to allow the installation of additional monitors. In addition the layout in all of the consultation rooms allowed patients to sit to the side of each GP and were able to view the computer screen.

#### **4.5.2 Use of GP computers**

All of the tasks undertaken by the GPs both during and outside patient consultation and the extent to which the computer and additional software applications were utilised were used to prepare an activity diagram which is shown in Figure 4.1. The initial activities undertaken by all of the GPs highlighted steps taken to reach the central patients' electronic health record (EHR) provided by each of the GP clinical system providers. After switching on their computers access to each of the GP clinical systems was from each desktop terminal by clicking on an icon and then using a user name and password. This process was simple in terms of time and ease of use for the GPs. Although for the Vision clinical system a greater number of steps were required as three separate logins were needed, two for Vision itself and one for Docman, an electronic database that managed scanned letters and communications.

All of the GPs used their computers throughout their working day for a wide range of both clinical and administrative tasks. In addition all of the GPs used NHS smartcards which allowed access to the NHS central care record (CRS). The actual level of use of GP practice computers including the GP clinical systems and additional functionality revolved around use during or outside of patient consultation.



**Figure 4.1 Activity diagram representing GPs' use of computers both during and outside of patient consultation.**



#### **4.5.2.1 SystmOne**

GP1, GP2 and GP3 all described the available functionalities of SystmOne as considerable with many different applications or features. Some of the positive aspects to the system included speed, ease of use, and the ability to quickly navigate between the various functions. However GP1 described the layout of the screen and the use of icons to display the array of functionalities as excessive. GP2 found some of the functionality around drug information and pricing particularly at the point of prescribing not as good as other GP clinical systems. SystmOne is a window - based hosted system and allows a level of external sharing and access to the clinical system and patient's health record. Once authorised users can access any patient held information from any GP practice where the clinical system is installed.

#### **4.5.2.2 EMIS**

GP4, GP5 and GP6 were all positive towards their experiences and use of the EMIS GP clinical system. GP4 was a user of EMIS LV, an older disk operated system (DOS) whilst GP5 and GP6 were users of EMIS Web, a window - based system. The layouts of each of the systems were completely different with users of EMIS LV mainly reliant on the keyboard to complete tasks. All of the GPs found EMIS quick and easy to use and found locating information a simple task. EMIS Web is a hosted GP clinical system and allows a certain level of external sharing and access to other users.

#### **4.5.2.3 Vision**

GP7, GP8 and GP9 described mixed experiences of using the window - based Vision GP clinical system. GP7 and GP9 found aspects of the system slow and the level of available functionality excessive. In addition both GP7 and GP9 described the level of training they received on Vision as inadequate. GP8 was extremely positive towards all aspects of the system and was a regular user of many of the available functions.

#### **4.5.3 Patient consultations**

The GPs described varying levels of use of their computers either prior to or during each patient consultation. Prior to a consultation use was dependent on time and knowledge of the individual patient. Appointment slots would indicate to the GP which patients were due to be seen each day. All of the GPs described the pressures of time constraints in relation to patient appointments and consultations.

Time permitting key areas of the patient's EHR that were checked were from attendance during recent consultations, previous recorded clinical problems or diagnosis, medication records, investigations and any hospital communications. During patient consultation nearly all of GPs tended to leave any use of GP clinical system towards the end of the consultation in order to record relevant details and or complete any tasks such as issuing a prescription. GP2 described that there was no time to even look at the computer screen during consultation whilst GP6 was definite that any use had to be reserved to the end of the consultation so that time was solely allocated directly to the patient. GP1, GP4 and GP8 all described being able to use their computers broadly to the same level both during and outside a patient consultation.

#### **4.5.4 Recording templates and read coding**

During patient consultations the ability of the GPs to utilise many of the electronic functions available was limited primarily due to time constraints. All of the GPs described the ability to record each consultation using a consultation recording template however only GP4, GP5, GP8 and GP9 actually used this functionality routinely. The other GPs all tended to record relevant aspects of each consultation using free text. Although other recording templates were available to support disease management these tended to be reserved where specific clinics such as in asthma or diabetes. Read coding was also described as problematic during consultations due to time constraints. In addition the GPs also described dissatisfaction with the level and accuracy of read coding performed by other users of the clinical systems within each of the GP practices.

#### **4.5.5 Prescribing**

All of the GPs described the process of issuing prescriptions for medication during consultations as one-off "acute prescriptions" for acute clinical indications with the patient present. For patients with long term conditions where regular medication was required, prescriptions would be initially generated by the GP on a "repeat" basis. Once authorised further repeat prescriptions were generated by practice staff at regular intervals for the GP to check and sign without the patient being present. The GPs all described prescribing as a quick and simple process in terms of generating both "acute" and "repeat prescriptions" and all demonstrated the prescribing workflow.

With the window-based systems (SystmOne, EMIS Web and Vision) a pop up template that guided the end user through the prescribing workflow was accessed by clicking on either an acute or repeat prescribing icon. Key features that required completion were the drug name, formulation, dose, quantity, and prescription type. A number of fields required completion either from drop down menus or manual entry and selection. The repeat prescribing templates differed slightly with additional fields around medication management systems such as numbers of issues permitted and when re-authorisation was needed. The prescribing workflow within EMIS LV was simpler in terms of visual appearance, data entry and overall completion. In addition the GPs who used SystmOne were able to prescribe from an installed prescribing formulary that had been approved for use within the local CCG.

All of the GPs described the availability of both active and passive CDSS within each of the GP clinical systems. Some of the passive CDSS alerts were available as integrated icons and directly visible or electronically available through links. However overall use during consultations of CDSS was generally limited to prescribing and active alerts linked to warnings such as drug interactions and safety messages. In general the decision making around how to treat the presenting condition during consultations was GP led and built around the patient rather than referring to the GP clinical system or any other additional software applications. Once a decision was made to prescribe, in the majority of cases the prescription was issued and although CDSS was clearly available during the prescribing workflow most of the active alerts generated were ignored. However all of the GPs described the availability of Script-Switch<sup>®</sup> and found this a useful resource at the point of prescribing. Drug specific information was available during prescribing workflow and could be accessed easily from within all of the window - based systems. The GPs who used SystmOne found drug pricing information difficult to obtain due to the number of additional steps required, particularly within the prescribing workflow.

#### **4.5.6 Referrals**

During consultations all the GPs described being able to refer patients using template letters that could be accessed from within each of the GP clinical systems. Electronic referrals were made using the national electronic system Choose and Book and were sent to a local referral facilitation service for checking and processing. The system allowed patients a choice of either NHS or private hospital out-patient appointments and was simple to access and use on all the GP clinical systems.

In addition GP5 and GP6 described the use of an electronic pathology system that the practice had recently introduced. The system allowed an electronic blood form to be printed and given to patients. This form was also sent automatically to the local pathology provider in advance of the patient presenting at the clinic.

#### **4.5.7 Computer use outside of consultation**

The GPs described their individual workload in relation to their clinical roles and the need to complete a specific level of administrative tasks each day. Time was generally set aside for each of the GPs to work on these areas at the end of surgery. These tasks included checking pathology results received electronically via lab links, dealing with letters and communications from hospitals e.g. discharge letters, out-patient prescriptions and results of investigations. These activities were generally conducted within the patient's EHR, as actions would often require recording and or follow up with patients. Paper letters were left for practice staff to scan and record into the patient's EHR. Some activities however required the additional use of computerised functionalities outside of the GP clinical system. The GPs described using a number of resources such as NHS mail, the internet, Microsoft applications and the local CCG extranet. All of the GPs found time to use a range of passive CDSS to provide information on specific drugs or diseases, including patient information leaflets either from within the GP clinical system, externally from desktop icons or by using the internet.

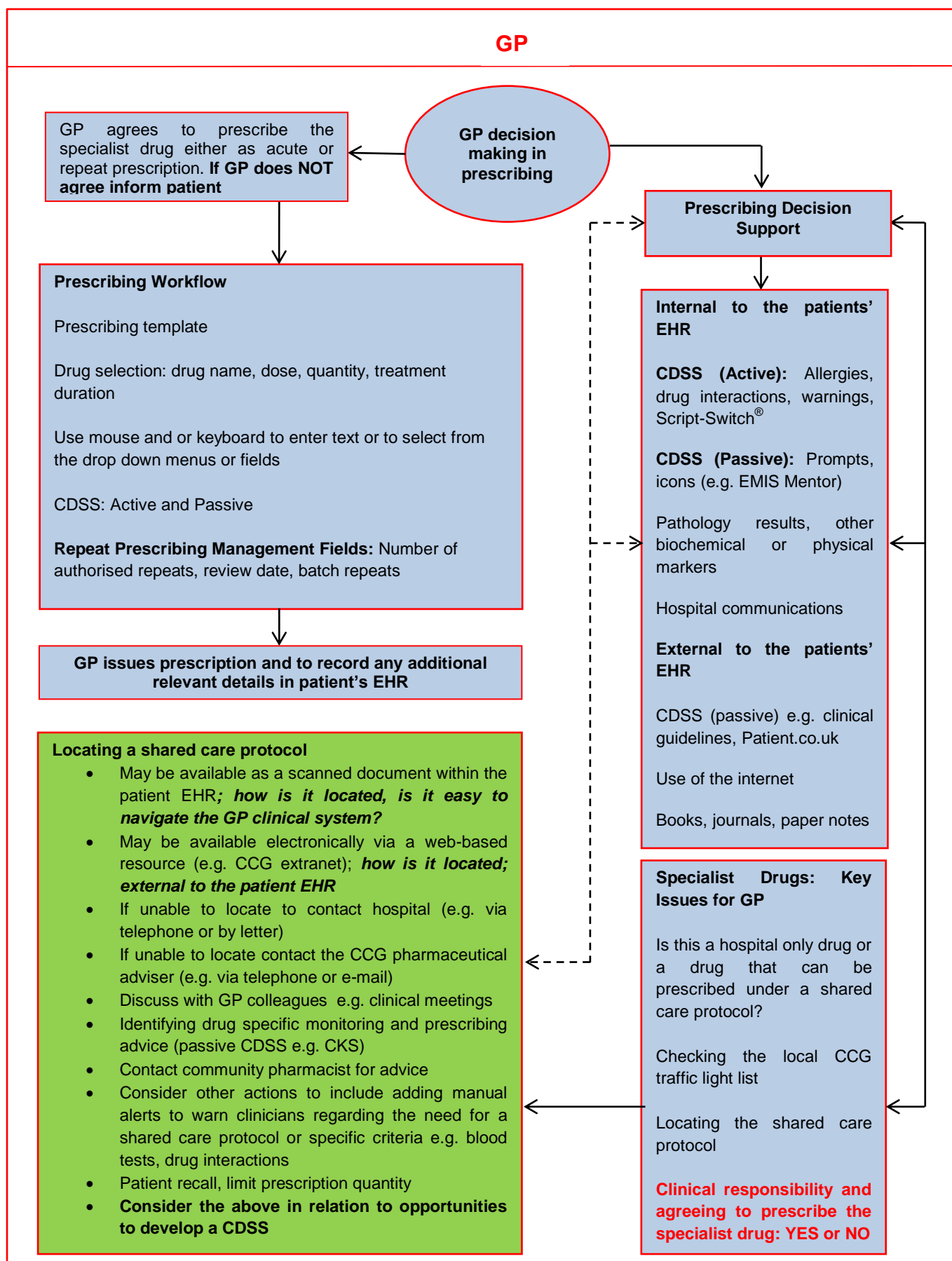
#### **4.5.8 GMS contract and locally commissioned services**

The GPs described varied levels of activities linked to attainment of QOF points and performance against enhanced services within the GMS contract. In addition other tasks carried out related to additional locally commissioned services. All of the GP clinical systems provided on-going data management and reporting facilities to provide practice performance in relation to QOF. The alerts provided by QMAS within each GP clinical system appeared as on-screen reminders with the patients' EHR highlighting the need for specific interventions. Only GP5 and GP8 described being able to process these reminders during the consultation, otherwise these tasks were left to be completed opportunistically. GP8 in particular described being an active user of this aspect of Vision to support additional work such as clinical audit and reporting. Both GP4 and GP8 worked at practices that offered local anticoagulation management under an enhanced service and were users of INRstar®.

#### **4.6 Case Scenario: Requests to prescribe specialist drugs**

The GPs described a range of tasks they would undertake in order to reach a decision as to whether to agree to requests to prescribe specialist drugs. These tasks were used to prepare an activity diagram shown in Figure 4.2. All of these tasks were affected by a number of factors such as the availability of relevant information, time constraints particularly within patient consultations and patient expectations. The GPs described similar approaches to the decision making process in agreeing to prescribe a specialist drug. Although there was a general awareness of local traffic light lists, this information was not easily available either within the GP clinical system or at the practice itself. Having to physically make enquires and locate information regarding traffic light lists or shared care protocols particularly during consultations was time consuming. GP1, GP3 and GP4 would specifically look for the local CCG traffic light list at the outset to check if the drug was a hospital only drug. GP1 described checking the availability of the traffic light list from the CCG extranet whilst GP3 and GP4 would contact the CCG pharmaceutical adviser.

In the absence of a shared care protocol all of the GPs described trying to gather drug specific information from a range of sources such as the BNF (paper and electronic), drug information portals from either within the GP clinical systems e.g. EMIS mentor or external websites accessed from the internet. In addition the GPs described difficulties in having to contact consultants in hospitals either by letter, fax or telephone. All of the GPs described having to make contact with the CCG pharmaceutical adviser for advice either by telephoning or sending an e-mail. Other options described were the use of the internet or known websites e.g. CKS to obtain either clinical aspects of shared care protocols such as monitoring or examples of shared care protocols from other hospitals. In addition any shared care protocol located still needed to be checked to determine if it was valid. An additional problem cited was the time required to document all of the additional tasks within the patients' EHR. The GPs all described the need to involve and inform patients at all times and in many cases patients' expectations were a key factor in the overall decision making. A specific point made by GP3 was that often in such scenarios the overall process and decision making was based on previous experiences and memory rather than any clear direction or steps to take including either any written procedures or computerised functionality within the GP clinical system.



**Figure 4.2 Activity diagram representing tasks involved in GPs' decision making in managing requests to prescribe specialist drugs**

#### **4.6.1 Prescribing specialist drugs**

The GPs described limited functionalities within each of the GP clinical systems to support in the on-going prescribing of specialist drugs. All of the GPs described being able to add simple alerts or reminders to patient's electronic health records to highlight that the patient was being treated with a specialist drug or that a shared care protocol needed to be followed. Additional tasks described were restricting prescription quantities of the specialist drug and or creating tasks such as recall in order to ensure patients attended the practice on a regular basis. GP8 described that in such cases these patients would always be discussed at practice clinical meetings to ensure all of the other GPs and staff were aware of any specific issues such as regular therapeutic monitoring. Where shared care protocols were available all of the GPs reported that they would be scanned and added to a patient's EHR. However an additional problem described was that the GPs relied on administrative staff for scanning letters and communications. Although the GPs described using each GP clinical system as quick and simple, locating a shared care protocol was not straightforward as scanned letters were filed by speciality so a number of documents needed to be checked before the shared care protocol was found.

#### **4.7 Hierarchical task analysis**

The GPs described various actions to the case scenarios presented, with the central aim of deciding whether or not to accept clinical responsibility for prescribing a specialist drug. The Hierarchical task analysis conducted was only applied to the physical task of prescribing specialist drugs and this is shown in Table 4.2. Essentially the overall task was simplistic with the goal being to prescribe the specialist drug. In addition key sub-tasks were identified. Firstly there needed to be a check to ensure if the specialist drug was not a hospital only drug In such cases the request to prescribe would be Declined. Secondly there was a check to assess if the specialist drug were prescribed by a GP whether or not a shared care protocol was required. These checks were made by referring to a traffic light classification of specialist drugs. The final sub-task was locating the shared care protocol.

**Table 4.2 Hierarchical task analysis of the prescribing of specialist drugs by GPs**

<b>Prescribing a specialist drug</b>
Plan 0: Either during or outside a patient consultation the GP needs to consider a request to prescribe a specialist drug. Do 1.1 to 1.4
1.1 To check the traffic light list and see if the specialist drug is a “ <b>hospital only drug.</b> ” If “Yes” the GP should <b>NOT</b> prescribe, and should refer back to the hospital clinic. If “No” go to 1.2
1.2 To check the traffic light list and see if the specialist drug can be prescribed under a shared care protocol. If “Yes” go to 1.3.
1.3 GP to locate the shared care protocol.
1.4 GP reads the shared care protocol and <b>agrees</b> to accept clinical responsibility for prescribing the specialist drug
1.5 GP reads the shared care protocol and <b>declines</b> to accept clinical responsibility for prescribing the specialist drug, inform patient

#### **4.7.1 SHERPA error analysis**

The SHERPA error analysis model categorises potential error types as either action error, checking error, retrieval error, communication error or selection error. Each error type can be further categorised as an error mode and specifically coded. These are described in Table 4.3. The application of SHERPA error analysis to the prescribing of specialist drugs by GPs is shown in Table 4.4. The SHERPA error analysis takes each task identified from the HTA and then categorises the error type, consequence, recovery, probability of occurrence (P) and remedial action or design solution. The probability of occurrence was described as high (H), medium (M) or low (L). The SHERPA error analysis demonstrated that although the specific task of prescribing was relatively simple in terms of the number of steps required to complete this task, the potential for error was considerable.

Under the description column the potential error that could occur was referenced against those specific GPs that referred to or described completing this specific task. Other potential errors came to light during that analysis, but were not described by any other GPs.



**Table 4.3 SHERPA error modes**

<b>Error Type</b>	<b>Code</b>	<b>Error mode</b>
Action errors	A1	Operation too long/short
	A2	Operation mistimed
	A3	Operation in wrong direction
	A4	Operation too little/much
	A5	Misalign
	A6	Right operation on wrong object
	A7	Wrong operation on right object
	A8	Operation omitted
	A9	Operation incomplete
	A10	Wrong operation on wrong object
Checking errors	C1	Check omitted
	C2	Check incomplete
	C3	Right check on wrong object
	C4	Wrong check on right object
	C5	Check mistimed
	C6	Wrong check on wrong object
Retrieval errors	R1	Information not obtained
	R2	Wrong information obtained
	R3	Information retrieval incomplete
Communication errors	I1	Information not communicated
	I2	Wrong information communicated
	I3	Information communication incomplete
Selection errors	S1	Selection omitted
	S2	Wrong selection made

Table 4.4 Application of SHERPA to the prescribing of specialist drugs by GPs

Task step	Error mode	Description	Consequence	Recovery	P	Remedial strategy / design solution
1.1 To check if the specialist drug is a “hospital drug.”	C1	Failure by GP to check the traffic light list (GP1, GP3, GP4, GP7)	A hospital only specialist drug is prescribed by the GP	At next request for prescription (1.1)	M	<p>Add / highlight to the patients’ EHR e.g. screen alert or manual reminder</p> <p><b>Design Solution: The GP clinical system to automatically alert the GP that this is a hospital only drug, not to prescribe and to refer back to the hospital i.e. a hard stop</b></p> <p>Community pharmacist informs GP that a hospital only drug has been prescribed.</p> <p><b>Design Solution: The pharmacy computer system to automatically alert the pharmacist that this is a hospital only drug and not to be issued in primary care and to refer back to the GP</b></p>
	R1	Traffic light list is not available at the practice (paper list) (GP1)	A hospital only specialist drug is prescribed by the GP	At next request for prescription (1.1)	H	<p>Add / highlight to the patients’ EHR e.g. screen alert or manual reminder.</p> <p>Practice to ensure paper list is available to all GPs including locums</p>
	R1	Traffic light list is available at the practice (paper list), <b>but is out of date</b>	A hospital only specialist drug is prescribed by the GP	At next request for prescription (1.1)	L	<p>Add / highlight to the patients’ EHR e.g. screen alert or manual reminder.</p> <p>Practice to ensure updated / current paper list is available to all GPs including locums</p>

Table 4.4 Application of SHERPA to the prescribing of specialist drugs by GPs (cont.)

Task step	Error mode	Description	Consequence	Recovery	P	Remedial strategy / design solution
1.2 To check if a shared care protocol is required to support the prescribing of a specialist drug	R1	Traffic light list is available at the practice (via local extranet) but lack of GP awareness (GP1)	A <b>hospital only</b> specialist drug is prescribed by the GP	At next request for prescription (1.1)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder
	R1	Traffic light list is available at the practice (via local extranet) but lack of GP access rights (GP1)	A <b>hospital only</b> specialist drug is prescribed by the GP	At next request for prescription (1.1)	H	To make a link available to local extranet web-page. Practice to ensure all GPs and locums have a user name and password
	C1	Failure by GP to check the traffic light list (GP1, GP3,GP7)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.2)	M	Add / highlight to the patients' EHR e.g. screen alert or manual reminder that a shared care protocol is required
	R1	Traffic light list is not available at the practice (paper list)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.2)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder. Practice to ensure paper list is available to all GPs including locums
	R1	Traffic light list is available at the practice (paper list), but is out of date	A specialist drug may be prescribed <b>without</b> reference to the <b>current</b> shared care protocol.	At next request for prescription (1.2)	L	Add / highlight to the patients' EHR e.g. screen alert or manual reminder  Practice to ensure updated / current paper list is available to all GPs including locums

Table 4.4 Application of SHERPA to the prescribing of specialist drugs by GPs (cont.)

Task step	Error mode	Description	Consequence	Recovery	P	Remedial strategy / design solution
1.3 To locate the shared care protocol to support the GP in prescribing the specialist drug.	R1	Traffic light list is available at the practice (via local extranet) but lack of GP awareness (GP1, GP8)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.2)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder
	R1	Traffic light list is available at the practice (via local extranet) but lack of GP access rights (GP1, GP8)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.2)	H	To make link available to local extranet web-page  Practice to ensure all GPs and locums have a user name and password
	R1	Shared care protocol not available to GP (paper copy) <b>as not sent by hospital clinic.</b>  GP unable to contact clinic and or receive shared care protocol (time constraints) (GP1,GP2, GP6, GP7)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder  Ensure hospitals send copies of shared care protocols to GPs (Action for Medicines Management Teams)
	R1	Shared care protocol not available to GP (paper copy) as filed in patient's paper notes and NOT scanned into patients' EHR (GP1)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	L	Ensure paper copy of shared care protocol is scanned into patients' EHR (for practice staff). Need to highlight in practice policy in handling communications from hospitals i.e. scanning in appropriately.  Add / highlight to the patients' EHR e.g. screen alert or manual reminder

Table 4.4 Application of SHERPA to the prescribing of specialist drugs by GPs (cont.)

Task step	Error mode	Description	Consequence	Recovery	P	Remedial strategy / design solution
	R1	Shared care protocol has been scanned into patients' EHR, but not easily available or difficult to locate (i.e. difficulty in navigating the clinical system)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	M	<b>Design solution: The GP clinical system to make the protocol easily available and or identifiable within the patient's EHR</b>  Training for GP on the use of the clinical system
	R1	Shared care protocol is not available via the local extranet (GP6, GP8)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	H	To ensure that the shared care protocol is available on local extranet (Medicines Management Teams)
	R1	Shared care protocol is available on local extranet but lack of GP awareness	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder
	R1	Shared care protocol is available via local extranet but lack of GP access rights	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	H	To make a link available to local extranet web-page (will need user name and password). Practice to ensure all GPs and locums have a user name and password
	R1	Shared care protocol is available via local extranet but out of date	A specialist drug may be prescribed <b>without</b> reference to the <b>current</b> shared care protocol.	At next request for prescription (1.3)	L	To ensure that the <b>current</b> shared care protocol is available on local extranet (Medicines Management Team)

Table 4.4 Application of SHERPA to the prescribing of specialist drugs by GPs (cont.)

Task step	Error mode	Description	Consequence	Recovery	P	Remedial strategy / design solution
	R1	Lack of GP awareness of availability of shared care protocols from other external web based NHS resources (GP1, GP2)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	At next request for prescription (1.3)	M	Add / highlight to the patients' EHR e.g. screen alert or manual reminder – with names of external web based NHS resources
	R1	Lack of GP awareness of prescribing support from other electronic or manual resources (drug specific e.g. drug interactions, monitoring) (GP1, GP3, GP9)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	Following issue of prescription, end of surgery (1.3)  At next request for prescription (1.3)	H	Add / highlight to the patients' EHR e.g. screen alert or manual reminder for checks to be made before next prescription due date
	R1	GP unaware of local CCG pharmaceutical adviser contact details (GP1, GP2, GP3, GP4, GP5, GP8, GP9)	A specialist drug may be prescribed <b>without</b> reference to the shared care protocol.	Following issue of prescription, end of surgery (1.3)  At next request for prescription (1.3)	M	Details of local CCG pharmaceutical adviser to be made available either at the GP practice and or within the GP clinical system

#### **4.7.2 Remedial Strategies and design solutions**

It was clear that the underlying problem that the GPs faced was dealing with a paper based communication system used by secondary care. The risk of prescribing specialist drugs in an unsafe manner was increased because of the lack of available functionality within all of the GP clinical systems and time constraints. In order to resolve these issues all the GPs required time. In addition some GPs relied on other staff to provide advice and information. In many cases the next opportunity to resolve such problems was when a further prescription was requested by the patient.

The predominant theme that emerged from the SHERPA error analysis was the almost complete application of the error mode R1 to each task because information required by the GP was not readily available. The potential adverse outcome was that a GP could inadvertently prescribe a specialist drug that was either classed as hospital only, or prescribe one without reference to an appropriate shared care protocol. In addition 11 out of the 20 task steps where an error could occur were rated as a high probability of occurrence. The fundamental problems described by the GPs related to the lack of awareness or availability of either the traffic light list or shared care protocols. In addition, where shared care protocols were required to support the prescribing of specialist drugs, a major obstacle was locating them in either a paper or electronic format. It was evident that throughout the whole process the currently available computerised systems, either from the GP clinical systems or from other software applications were unable to provide support or solutions to the problems described by the GPs. The easiest remedial solution to the problems described by the GPs was to physically add simple alerts or reminders to the patients' EHR. These alerts allowed free text to be added to a pop up box that could inform each user of key messages in relation to the prescribing of specialist drugs, such as to check the shared care protocol or the need for regular blood tests. .

Other interventions described were manual tasks to contact and liaise with a range of individuals such as GPs, practice staff, primary care pharmacists within CCG medicines management teams and clinical teams within secondary care. Potentially either GP clinical systems or community pharmacy computer systems could incorporate active hard stops to alert users of when hospital only drugs were being prescribed. However this could also be effectively incorporated within a novel prescribing support module i.e. an electronic management of specialist drug CDSS inclusive of all specialist drugs.

Based on the results from the previous key informant interviews, the hierarchical task analysis and SHERPA error analysis a potential operating model for a CDSS to support GPs in prescribing specialist drugs was identified. Table 4.5 describes a hierarchical task analysis of this proposed model to demonstrate how a GP could potentially safely prescribe a specialist drug in primary care.

**Table 4.5 Hierarchical task analysis of the prescribing of specialist drugs by GPs (Potential operating model supported by CDSS)**

<p><b>Prescribing a specialist drug</b></p> <p>Plan 0: Either during or outside a patient consultation the GP needs to consider a request to prescribe a specialist drug. Do 1.1 to 1.9</p> <p>1.1 To check if the specialist drug can be prescribed in primary care by a GP</p> <p>1.2 Enter the “<b>Management of Specialist Drugs Module</b>” integrated within the GP clinical system.</p> <p>1.3 Enter the drug name, and confirm if the specialist drug is a <b>hospital only drug or one that requires a shared care protocol</b>. If hospital only follow the prompt to exit and inform the patient.</p> <p>1.4 If a shared care protocol is required follow the prompt to direct the GP to the shared care protocol section of the module.</p> <p>1.5 Module to automatically update fields for monitoring requirements within electronic shared care protocol from a search of patient’s EHR</p> <p>1.6 If data not available within patients’ EHR, module to automatically prompt action or task e.g. full blood count</p> <p>1.7 GP to decide whether to accept clinical responsibility for prescribing the specialist drug. If “No” exit and inform patient; if “Yes” go to 1.8.</p> <p>1.8 Once satisfactorily completed select the prompt within the module to the prescribing functionality, follow the <b>prescribing workflow</b> and issue prescription (consider repeat or acute prescription).</p> <p>1.9 Module to save all recorded information appropriately and with relevant read code within patients’ EHR on exit and automatically update the prescribing authorisation and or review date.</p>
--



#### **4.8. Discussion**

In 2001 the Department of Health established the National Patient Safety Agency (NPSA) with a mandate to identify patient safety issues and find appropriate solutions. The NPSA has produced key guidance for health professionals in the NHS that has introduced both human factors techniques such as to support designing healthcare settings (NPSA 2010) and in applying risk assessment methods to include predictive safety analysis techniques such as failure mode and effect analysis (FMEA) and probabilistic risk assessment (NPSA 2006). Both of these reports have cited the wide experience of such methods and techniques from the commercial sector particularly critical industries.

This is the first study that has applied both hierarchical task analysis and an error analysis model (SHERPA), to the task of prescribing specialist drugs by GPs in the UK. Kirwan (1998) described 38 predictive error analysis models which have been developed including SHERPA and FMEA. However their use within UK healthcare settings has remained limited and reserved to secondary care settings. The results from this study highlighted key areas of potential risk in the prescribing of specialist drugs and use of shared care protocols. A key aspect that emerged was the risk associated with a lack of awareness or access to either traffic light classification lists or shared care protocols themselves. Navigating extranet sites was described as difficult even for GPs who reported themselves as IT literate, compounded by time constraints during patient consultations. Crowe et al (2009) undertook qualitative interviews with stakeholders (n = 47), including 14 GPs on the factors that influenced GP decision making in prescribing specialist drugs. Of six diverse factors identified one was described as a locally agreed advisory lists (red, amber or green). Key drawbacks were reported with traffic light classification lists linked to GPs' lack of understanding of these lists, inadequacies in dissemination and communication from PCTs and poor distribution at practice level. In addition a specific concern with the use of traffic light lists was the amber classification for specialist drugs where a shared care protocol did not exist, which in effect meant that these drugs would be treated as them red or hospital only drugs. In addition the authors reported there were frequent requests asking GPs to prescribe specialist drugs without a shared care protocol being provided.

The 9 GPs who participated in the current study used the three major GP clinical systems in the UK EMIS, Vision and SystmOne. The results from the HTA and SHERPA error analysis identified barriers in terms of managing requests to prescribe specialist drugs. In general the GPs worked in a similar way and the tasks carried associated with requests to prescribe specialist were not affected by or dependant on the GP clinical system used.

#### **4.9. Limitations**

GP1, GP2 and GP3 participated in the key informant interviews, although GP3 was only involved in an initial pilot. In addition all of the GPs worked within a single CCG, and were purposively selected as they known to the lead researcher and this may have introduced bias. In addition all of the GPs were young with the most experienced GP having qualified in 2001. In addition all of the GPs described themselves as having either good or high IT aptitude, and this may have introduced bias in terms of the level and use of computers, GP clinical systems and CDSS. In addition the HTA was only applied to the process of prescribing and was not applied to the patient consultation, decision making around agreeing to prescribe a specialist drug and the prescribing workflow itself. This would form the basis of further research in this area.

#### **4.10. Further work**

Only 9 GPs were recruited although they represented users of the three main GP clinical systems available in the UK. Therefore further work should be extended to include a larger sample of GPs, randomly selected and with a varied background and level of experience of both IT in general and use of GP clinical systems. In addition this sample should include sessional GPs and locums. In addition further work could include investigating additional aspects of GP workload and use of computers. This could include decision making during consultation, supporting diagnosis and prescribing workflow.

Although HTA was chosen as the preferred research method in this study the results from the SHERPA error analysis identified a need to further explore the decision making processes followed by GPs. This would be achieved by adopting a cognitive approach to task analysis and should inform the process of further research in this area. Published evidence from the UK of the use of cognitive task analysis within healthcare settings is limited.

In an extension to a previous study Phipps et al (2011) explored some of the cognitive aspects in relation to the planning and delivery of anaesthesia by applying two alternative extensions to the standard hierarchical task analysis. The authors described the value of generating insights in the way anaesthetists handled information and their own cognitive performance. In terms of GP decision making and the use of CDSS to support the prescribing of specialist this is as yet an unexplored area, and would form a clear basis for further research.

#### **4.11. Conclusion**

A study of human ergonomics was used to further investigate GPs and the actual level and use of computers and software programs including CDSS at the point of prescribing both during and outside of patient consultations. The application of an analytical approach to these processes through a task analysis framework and specifically a predictive error analysis (SHERPA) identified failings in existing arrangements for GPs to safely prescribe specialist drugs. The lack of specific functionality within GP computer systems including CDSS adversely affected the ability for GPs to resolve problems associated with the prescribing of specialist drugs. Time constraints during patient consultations compounded these problems. A potential operating model to support GPs in the prescribing and use of specialist drugs has been identified based on the use of hierarchical task analysis and the application of the SHERPA error analysis model.

# **Chapter 5**

## **General Conclusion**

## **5.1 Overview**

This thesis investigated developing a novel CDSS to aid GPs in the prescribing and management of specialist drugs in primary care. One of the aspects to this investigation was to explore this concept with a range of stakeholders. This work was further extended with GPs, as end users of a potential system. The background to this thesis was GP prescribing in the UK with a focus on the principles that defined and measured prescribing quality. Based on a literature review (Barber 1995) and findings from the World Health Organisation (WHO 2002), the National Prescribing Centre (NPC) defined prescribing quality as a balance of the traditional teaching of safety and efficacy with the need to be cost-effective and involving the patient in treatment (NPC 2007). Duerden et al (2011) reported that definitions of prescribing quality were elusive and that any description was guided by the stakeholder groups involved in the prescribing process.

From a NHS management perspective regulation in the use of medicines has been influenced by the emergence of national bodies and agencies that have been tasked to address key aspects that have had a major influence GP prescribing. Cost containment has consistently been an issue for the NHS ever since its inception in 1948. In the last 20 years prescribing has been under the scrutiny of the National Audit Office (NAO), Published reports from the NAO highlighted potential savings in expenditure from inappropriate prescribing (NAO 1994), increasing cost pressures linked to quality standards from National Service Frameworks (NSFs) and NICE (NAO 2003) and initiatives to improve prescribing efficiencies and reducing wastage (NAO 2007). Launched in 1999 as a Special Health Authority, NICE was made responsible to disseminate clinical guidelines on the relevant evidence of clinical cost effectiveness with the associated audit methodology and information on good practice (Stephens 2005). The UK Chief Medical Officer's report "An Organisation with a Memory" (Department of Health 2000) set out a challenging agenda for improving care by reporting and learning from adverse events, which later saw the establishment of the National Patient Safety Agency (NPSA). In the UK attempts to implement measures to improving prescribing quality have included the use of prescribing formularies, prescribing indicators and financial incentives through prescribing incentive schemes and clinical elements within the GMS GP contract. Developments in IT and the potential for CDSS to improve prescribing quality were identified as a research area. This was explored further by firstly scoping the evidence base of CDSS, and then investigating the potential of developing a novel CDSS to support GPs in the use and management of specialist drugs.

## **5.2 Scoping review**

One of the aims of this thesis was to identify the evidence base in relation to the use of CDSS in primary care. From the scoping review conducted experience of CDSS was identified in a wide range of clinical areas such as disease management, drug dosing, therapeutic control and prescribing. In the UK CDSS was found to be extensively available to GPs, particularly through GP clinical systems. However robust evidence in terms of randomised controlled trials were limited to use in anticoagulation management or evaluations of CDSS that were either prototypes or are no longer in use. In addition key problems associated with CDSS were identified including low usage rates, over-alerting, and to ensure that future developments were made by engaging closely with end users. In this study time constraints and a lack of resource meant engagement with stakeholders was limited. Other scoping reviews have demonstrated the benefits of wider engagement with stakeholders such as interviews, surveys and focus groups (Bissell et al 2008, Duerden et al 2011). This aspect was a key element in the research described in this thesis by identifying key informants and ensuring relevant stakeholders were identified and invited to participate.

## **5.3 Key informant interviews**

The aim of this study was to assess the feasibility of developing a CDSS to support GPs at the point of prescribing in the use and management of specialist drugs. Twelve key informants participated in this research study and represented four stakeholder groups. The informants described a broad range of views and experiences of information technology, use of computers and of specialist drugs. Three primary themes emerged from these interviews; safety in relation to the use of specialist drugs, information technology and costs. In terms of specialist drugs safety concerns were clearly evident and correlated with the published literature particularly with the use of shared care protocols (Horne et al 2001, Duggan et al 2001). All of the informants were positive towards the potential of a CDSS to support the use of specialist drugs and described potential operating models including enablers and barriers to implementation. Costs were described as a factor in terms of drug expenditure, NHS services and in funding arrangements for general practice to include CDSS. In principle key elements of operation and implementation for a potential CDSS were identified. Further evaluation of the potential CDSS was identified which required more detailed examination of how GPs, as end users, interacted with computers and CDSS.

## 5.4 Task analysis

This is the first study that has applied both hierarchical task analysis and an error analysis model (SHERPA), to the task of prescribing specialist drugs by GPs in the UK. Previous examples where these methods have been used within UK healthcare settings have been in secondary care (Joice et al 1998, Lane et al 2006, Phipps et al 2008, Phipps et al 2011). Operating within a paper based communication system from a secondary care was a fundamental obstacle for the GPs. Risks associated with the use of specialist drugs were compounded by the lack of available functionality within all of the GP clinical systems. Almost all of the error modes for each task were classed as retrieval errors due to the unavailability of the required information. There was a lack of functionality within GP clinical systems to resolve the problems associated with the prescribing of specialist drugs. Based on the results of the SHERPA error analysis the hierarchical task analysis was repeated and an operating model for a potential CDSS to support GPs in the use of specialist drugs in order to ensure high level safety and quality in prescribing was identified.

### 5.4.1 Extending the evidence base of CDSS

The key informant interviews and follow up task analysis were conducted between May 2012 and February 2015. During the analysis of the results of these studies new emerging data was identified in relation to the evidence base of CDSS. Some of this data was identified as a direct result of these studies. The key informants described key developments in terms of accreditation of CDSS, both in the UK (NICE 2013) and within the European Union (EMA 2012). One CDSS supplier introduced new products for use within primary care settings in the UK. In addition a number of published studies have reported on evaluations of CDSS in use, CDSS in development and of the literature including systematic reviews.

In the UK, medicines optimisation has been defined as a “patient-focused approach to getting the best from investment in and use of medicines that requires a holistic approach, an enhanced level of patient centred professionalism, and partnership between clinical professionals and a patient” (Picton and Wright 2013 p3). This national initiative is underpinned by four principles; to understand the patient's experience, evidenced based choices of medicines, ensure medicines are used safely and to incorporate medicines optimisation into routine practice. In order to support the implementation of medicines optimisation a recent development has been the introduction of a new CDSS in the UK by First Databank. OptimiseRx® is a system that is fully integrated within the workflow of SystemOne and can provide patient specific alerts based on a range of read coded health data (Anon 2015b).

Whereas OptimiseRx<sup>®</sup> is available at the point of prescribing, AnalyseRx<sup>®</sup> is a retrospective analytical tool also recently introduced by First Databank that provides a clinical reporting system based at both population and patient level to support CCGs, GP practices, prescribers and patients (Anon 2015c). At patient level the tool supports interventions in terms of case finding, clinical audit and patient specific medication plans.

CDSS such as OptimiseRx<sup>®</sup> and Script-Switch<sup>®</sup> provide decision support at the point of prescribing in the form of alerts which can also be tailored to the needs of the end user. An advantage of OptimiseRx is that alerts can take into account specific read coded elements of the patient's electronic health record. Both of these tools allow information messages to be authored in relation to safety warnings, including local traffic light classification of specialist drugs and the ability to add electronic links to websites or electronic portals where shared care protocols are available. Although this can provide an element of support in the decision making process as to whether a GP decides to prescribe any drug, including a specialist drug (see Fig 4.2), in the case of shared care protocols links within alerts will only take the end user to an electronic paper or PDF document. In contrast the HTA (Table 4.5) provides a potential solution in the form of a wholly electronic integrated management of the prescribing and use of specialist drugs.

In the UK Hayward et al (2013) used video recordings of patient consultations to examine the use of CDSS during patient consultations with GPs. This study used video recording of 112 patient consultations involving eight GPs based in three practices. During 73 of these consultations 132 prescriptions were issued which also generated a total of 117 CDSS alerts. However these alerts only resulted in the GP making a check on the prescription in only 3 cases and in each case no change was made to the prescription. The authors described the poor impact made by CDSS during consultations and suggested this was because by the time an alert had appeared the majority of the work required by the GP had already occurred because the GP has already consulted with the patient and formulating a decision around treatment options. The authors concluded that CDSS would be more acceptable and effective if the prescribing support was made much earlier during the process of prescription generation.

In the first published study of the views and or perceptions of GPs towards Script-Switch<sup>®</sup> Hire and Rushforth (2013), reported on the findings from semi-structured interviews with 8 GPs across 5 practices in the North of England. Key themes identified from a thematic analysis included acceptance, impact, external control, disruption to workflow and willingness to switch medication from either a GP or patient's perspective.



Despite general acceptance of Script-Switch<sup>®</sup> in terms of enhancing cost effective prescribing, its impact was perceived as limited compared to other existing cost effective prescribing initiatives. Key drawbacks cited included alert content, inability to filter alerts, a lack of GP control and a lack of integration with other clinical information held in the patient's electronic record. Despite these findings the uptake of Script-Switch<sup>®</sup> has increased since the scoping review and is now installed in over 7,500 GP practices (Anon 2015). A recent Dutch study has reported on the development of a CDSS to specifically focus on supporting medication reviews in elderly patients within nursing homes (De Wit et al 2013). The authors described five phase study to include the development of a CDSS, clinical rules to incorporate laboratory and pharmacy data, CDSS validation, randomised trial and feasibility for implementation.

In a recent literature review of all systematic reviews in relation to CDSS (Cresswell et al 2012) identified 41 systematic reviews of CDSS published between 1997 and 2010 that met their inclusion criteria which included impact on safety, quality or organisational, implementation or adoption consideration. Ten of the 41 systematic reviews had been identified from the scoping review conducted for this thesis. In addition the authors had used additional databases such as the Cochrane Library and personal databases which provided additional data. The authors reported on the improving evidence to support CDSS such as in clinical performance, but also highlighted risks with disruption to clinical workflow and the need for development to also be tailored towards the needs of end users. In a meta-regression of 162 randomised trials of CDSS, Roshanov et al (2013) evaluated the effectiveness of systems as reported outcomes of process of care or patient health. CDSS that presented advice in electronic charting or order entry system interfaces were less likely to be effective. Better outcomes were produced where CDSS provided advice for both patients and clinicians, where clinicians were required to supply a reason for overriding an alert or where a CDSS was evaluated by their developers.

## **5.5 Limitations**

There were a number of limitations with the studies that were conducted as part of this thesis. The main limitation of the scoping review was the availability of resources to further engage with stakeholders. This was a particular problem as other sources where evidence could have been obtained were not accessed such as attending conferences or seeking the views or experiences individuals either from interviews or surveys. In terms of the key informant interviews of the 12 key informants only two were GPs and only 2 NHS IT managers were recruited to the study.

Three of the GPs that participated in the final task analysis also took part in the key informant phase although one was only involved in a pilot phase. Overall the two studies that involved participants for this thesis were small and would have benefitted with having a larger and more diverse range of specific individuals based across a wider geographical area, particularly the GPs and secondary care clinicians. The stakeholder groups in the key informant interviews were not equally balanced. Additional senior NHS IT managers, including those working for the former NHS Connecting for Health, could not be recruited to participate in this study. In both the key informant interviews and the task analysis study the GPs were generally younger and more familiar with computers and IT systems

### **5.6 Implications for clinical practice and policy**

The results from this study have highlighted key safety concerns and issues with the use of specialist drugs, particularly when prescribed by GPs in primary care despite the availability shared care protocols. The secondary care clinicians involved in this study described from their first hand experiences with patients who had been prescribed immunosuppressant drugs and had suffered adverse effects following inadvertent switches in brands of tacrolimus. Clinical practice and policy key themes that emerged from the key informants were the repatriation of prescribing of immunosuppressant drugs and use of homecare services to deliver medication. Devaney and Lee (2013) have described the repatriation of immunosuppressant drugs in renal transplantation but it is not clear whether this may be extended to other transplant services and or other specialist drugs. This may have an impact on a potential CDSS if prescribing responsibility remains with secondary care clinicians, particularly with the extended roll out of electronic prescribing systems in secondary care. Going forward constraints in the UK economy are shaping the design and provision of a greater primary care led NHS. If GP commissioning is to continue with these increased pressures there are implications for the individual stakeholder groups such as commercial providers of CDSS in terms of future funding streams either for existing services or for future developments.

A range of potential funding models were explored with the key informants including GP funding, central funding and the current NHS funded model. The consensus was that either central funding from the Department of Health or an extension of current arrangements with local NHS organisations would be appropriate. None of the informants supported a GP funded model. One source of funding which could be explored was the potential use of savings generated by moving transplant clinics from secondary care to primary care.

### **5.6.1 Implication for GPs**

If GPs were to undertake the prescribing of specialist drugs fully supported by an integrated clinical module with CDSS, there would be implications on prescribing expenditure and increased workload for practices. This would be related to patient management such as more appointments and monitoring. There would also be a number of additional factors to take into account such as, accepting both clinical responsibility and the associated workload.

### **5.6.2 Implications for Clinical Commissioning Groups**

For CCGs there would be implications for overall financial management based on associated cost shifting from secondary care to primary care. In addition there would be requirements associated with clinical risk and governance arrangements around prescribing specialist drugs at practice level. In addition other financial implications would involve funding arrangements for a CDSS and whether it would be an associated cost linked to GP clinical system providers. The transfer of services from secondary care would require scrutiny for any savings generated could be linked to the development costs of a potential CDSS.

### **5.6.3 Implications for CDSS suppliers**

There would be a number implications for the CDSS suppliers, and this would be dependent on whether this would be an independent clinical module provided by a third party supplier or something developed by an existing GP clinical system provider. Key aspects would be IT governance, maintenance, updating and funding streams. The key informants described some of the current funding models for both GP clinical system providers and third party CDSS providers. The informants described a number of current funding streams where payment was outside the GPSOC licence fee arrangement with GP clinical system providers. These included through pharmaceutical industry advertising for DXS<sup>®</sup> and from cost savings generated by prescribing budgets for Script-Switch<sup>®</sup>. The informants described a number of initiatives for either planned developments or potential improvements in current CDSS including drug dosage management, disease management and care pathways to include diagnostics and investigations and supporting linkages between GP clinical systems and community pharmacy clinical systems.

### **5.6.4 Enablers and barriers to implementation**

The key informants all identified both enablers and barriers to the concept. Key enablers described included data quality and functionality, joint development and implementation, for the CDSS to have an active alerting functionality within an electronic patient record, and to make use of existing systems and frameworks. Key barriers described included addressing the needs of end users, security and regulation, and funding.

Although costs were not cited as a specific issue, recent NHS financial constraints may still have an impact depending on Government plans following on from the recent general election NHS Connecting for Health ceased to operate in 2013, and the longer term plans for electronic prescribing in secondary care are not known despite recent commitment (NHS England 2013).

## 5.7 Further Work

A range of opportunities for further work were identified to extend the knowledge base of CDSS. These included wider evaluations of the CDSS available within GP clinical systems included those provided via links and or arrangements with third part suppliers. One clear area identified was the need for further evaluations of existing CDSS such as Script-Switch® and INRstar.® A specific area would be to investigate not just the views of end users but also the commissioners who decide funding arrangements for the provision of these systems, including lead pharmacists from medicines management teams. The key informants described a number of operating models for a CDSS. These included primary care and secondary care together with homecare services. This would need to be further evaluated particularly with the anticipated increased uptake in the UK of electronic prescribing systems in secondary care (Ahmed et al 2013).

One of the enablers identified to support implementation was better use of existing frameworks. With primary care GP clinical system providers moving to hosted with wider external user access this would be a potential research area. Thistlethwaite et al (2010) described decision making in prescribing as complicated, involving both patient and doctor with a range of factors that influence this process including the use of a patient centred approach to prescribing. The results from the SHERPA error analysis identified a need to further explore the decision making processes followed by GPs. In terms of task analysis, this would be in the form of cognitive approaches. Any additional work in this area would need to involve a larger sample involving GPs including both GPs employed on a sessional basis, locums and GP registrars. This research should ideally consider patient views and experiences.

## 5.8 Overall Conclusion

The three aims of this thesis were to identify the evidence base in relation to the use of CDSS, to assess the feasibility of developing a novel CDSS and to identify an operating model for a potential CDSS to support GPs in the use of specialist drugs. In terms of outcomes all of these aims were met.

In addition on two key areas of new knowledge in relation to the subject area were identified which were:

- A potential operating model for general practice to support GPs in the prescribing and use of specialist drugs
- Key enablers and barriers to support the implementation of such a model

Safety was a primary focus of the research described in this thesis and the research conducted. The better use of information technology and CDSS may provide a solution but the results of this research suggest any new developments need to be carefully planned with implementation based around the needs and requirements of patients and clinicians.

## References

Ahearn M, Kerr SJ (2003). General practitioners' perceptions of the pharmaceutical decision support-tools in their prescribing software. *The Medical Journal of Australia*; 179: 34-37

Ahmed Z, McLeod MC, Barber N, Jacklin A, Franklin BD (2013). The use and functionality of electronic prescribing systems in English acute NHS Trusts: A cross-sectional survey.

*Plos One*; 8 (11): e80378. Doi10.1371/journal.pone.0080378

Available at:

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0080378#pone-0080378-g003>

(Accessed November 24<sup>th</sup> 2013)

Anderson S, Allen P, Peckham S, Goodwin N (2008). Asking the right questions: Scoping studies in the commissioning of research on the organisation and delivery of health services. *Health Research Policy and Systems*; 6:7 doi:10.1186/1478-4505-6-7doi:10

Available at: <http://www.health-policy-systems.com/content/6/1/7>

(Accessed 21<sup>st</sup> February 2015)

Anon (1989). Local drug formularies – Are they worth the effort? *Drugs and Therapeutic Bulletin*; 27 (4): 13-16

Anon (2008). Local Enhanced Service for Shared Care Prescribing. Service Outline for April 2008 – March 2009. Richmond and Twickenham Primary Care Trust. London

Anon (2010a). The computer says no. *Drugs and Therapeutic Bulletin*; 48: 37

Anon (2010b) Derbyshire Medicines Management and Guidelines. Traffic Light Classification for prescribing. Available at:

<http://www.derbyshiremedicinesmanagement.nhs.uk/images/content/Trafficlights/Traffic%20light%20classification%20December%20amended%202010.pdf>

(Accessed 5<sup>th</sup> December 2010): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis

Anon (2011a). Script-Switch® (Homepage). Available at: <http://www.scriptswitch.com/>

(Accessed 16<sup>th</sup> March 2011)

Anon (2011b) INRstar – safe, effective anticoagulation support.

Available at: <http://www.inrstar.co.uk/About/INRstar>

(Accessed 5<sup>th</sup> December 2011)

Anon (2012) Moving specialised medicines out of hospital.

Drugs and Therapeutics Bulletin; 50: 11

Anon (2015a). Script-Switch® (Homepage). Available at: <http://www.scriptswitch.com/>

(Accessed 16<sup>th</sup> February 2015)

Anon (2015b). OptimiseRx.

Available at:

<http://www.fdbhealth.co.uk/~media/downloads/form%20required/uk/datasheet%20-%20fdb%20optimiserx.ashx>

(Accessed 24<sup>th</sup> August 2015)

Anon (2015c). AnalyseRx.

Available at:

<http://www.fdbhealth.co.uk/~media/downloads/form%20required/uk/datasheet%20-%20fdb%20analyserx.ashx>

(Accessed 24<sup>th</sup> August 2015)

Armstrong R, Hall BJ, Doyle J, Waters E (2011). Cochrane Update

Scoping the scope of a Cochrane review. Journal of Public Health; 33 (1): 147 -150.

Arskey H, O'Malley L (2005) Scoping studies: Towards a methodological framework.

International Journal of Social Research Methodology 8 (2); 19-32

Ashworth M, Golding S, Shephard L, Majeed A (2002). Prescribing incentive schemes in two NHS regions. British Medical Journal; 234: 1187-1188

Ashworth M, Lea, Gray H, Gravelle H, Majeed A (2003). The development of prescribing incentive schemes in primary care: a longitudinal survey.

British Journal of General Practice; 53, 268 – 470

Ashworth M, Lloyd D, Smith R, Wagner A, Rowlands G (2007). Social deprivation and statin prescribing: A cross- sectional analysis using data from the new UK general practitioner Quality and Outcomes Framework. *Journal of Public Health*; 29, 1: 40-47

Austin SM, Balas EA, Mitchell JA, Ewigman BG (1994). Effect of physician reminders on preventive care: meta-analysis of randomized clinical trials.

Proceedings of the Annual Symposium on Computer Application in Medical Care.

American Medical Informatics Association; 121-124

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2247964/pdf/procascamc00001-0143.pdf>

(Accessed 8<sup>th</sup> July 2011)

Avery AJ (1998). Appropriate prescribing in general practice: Development of the indicators. *Quality in Health Care*; 7: 123

Avery AJ, Savelyich BSP, Sheikh A, Cantrill J, Morris C, Fernando B, Bainbridge M, Horsfield P, Teasdale S (2005). Identifying and establishing consensus on the most important safety features of GP computer systems: e-Delphi study.

*Informatics in Primary Care*; 13: 3-11

Avery AJ, Savelyich BSP, Sheikh A, Morris C, Teasdale S (2007). Improving general practice computer systems for patient safety: Qualitative study of key stakeholders.

*Quality and Safety in Healthcare*; 16: 28 - 33

Avery T (2010a). Prescriber 1990-2010: 20 years of increasing complexity.

*Prescriber*; 21 (7): 8-10

Avery T (2010b). Avoidable prescribing errors: Communication and monitoring.

*Prescriber*; 21 (6): 44-46

Avery AJ, Ghalen M, Barber N, Franklin BD, Armstrong SJ, Serumaga B, Dhillon S, Freyer a, Howard R, Talabi O, Mehta RL (2013). The prevalence and nature of prescribing and monitoring errors in English general practice: A retrospective case note review.

*British Journal of General practice*; e543-e553

Available at: <http://bjgp.org/content/bjgp/63/613/e543.full.pdf>

(Accessed 24<sup>th</sup> August 2015)



Barber N (1995). What constitutes good prescribing? *British Medical Journal*; 310: 923 - 925

Barber N (2004). Designing information technology to support prescribing decision making. *Quality and Safety in Healthcare*; 13: 450-454

Barr F (2008). Moving to hosted systems.

Available at: <http://www.digitalhealth.net/features/43153/>

(Accessed 11<sup>th</sup> October 2015)

Bateman DN, Soutter J, Eccles M, Roberts S J, Campbell M, Smith JM (1996).

Setting standards of prescribing performance in primary care: Use of a consensus group of general practitioners and application of standards to practices in the north of England.

*British Journal of General Practice*; 46: 20 – 25

Bell DS, Cretin S, Marken RS, Landman AB (2004). A conceptual framework for evaluating out-patient electronic prescribing systems based on their functional capabilities.

*Journal of the American Informatics Association*; 11: 60-70.

Bennett JW, Glasziou PP (2003). Computerised reminders and feedback in medication management: A systematic review of randomised controlled trials.

*The Medical Journal of Australia*; 178: 217-222

Bennett JW, Glasziou, P, Del Mar C, De Looze F (2003). A computerised prescribing decision support system to improve patient adherence with prescribing. *Australian Family Physician*; 32 (8): 667-671

Benson T (2002). Why British GPs use computers and hospital doctors do not (Part 1 Incentives). *British Medical Journal*; 325: 1086-1089

Benson T (2010). *Principles of Health Interoperability HL7 and SNOMED*. London: Springer

Besley J (2009). What is evidenced based medicines? Available at:

<http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/ebm.pdf>

(Accessed 24<sup>th</sup> April 2012)

Bissell P, Cooper R, Guillaume L, Anderson C, Avery A, Hutchinson A, James V, Lymn J, Marsden E, Murphy E, Ratcliffe J, Ward P, Woosley I (2008). An Evaluation of Supplementary Prescribing in Nursing and Pharmacy.

Available at: [http://eprints.whiterose.ac.uk/76239/1/Supplementary\\_prescri:](http://eprints.whiterose.ac.uk/76239/1/Supplementary_prescri:)

(Accessed 21<sup>st</sup> February 2015)

Bland D (2008). The New General Practitioners. (GP) contract: improving the way healthcare is delivered in the UK. British Medical Association.

Available at [http://www.bma.org.uk/images/QOFbrief0908\\_tcm26-178056.pdf](http://www.bma.org.uk/images/QOFbrief0908_tcm26-178056.pdf)

(Accessed 9<sup>th</sup> May 2010): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis

Bostock N (2007) GPs demand reprieve for Prodigy. Available at

<http://www.gponline.com/News/article/625331/GPs-demand-reprieve-Prodigy/>

(Accessed 1<sup>st</sup> November 2012)

Bradley C (1991). Decision Making and Prescribing Patterns: A literature review. Family Practice; 8: 276-287

Brien S, Lorenzetti D, Lewis S, Kennedy J, Ghali W (2010). Overview of a formal scoping review on health system report cards. Implementation Science; 5:2.

Available at: <http://www.biomedcentral.com/content/pdf/1748-5908-5-2.pdf>

(Accessed 13<sup>th</sup> May 2015)

Britten N, Jones R, Murphy E, Stacy R (1995). Qualitative research methods in general practice and primary care. Family Practice; 12 (1): 104-114

Britten N (2001). Prescribing and the defence of clinical autonomy.

Sociology of Health and Illness; 23 (4): 4

Britton L (2009). The history of The BNF. Available at: [http://www.pjonline.com/tomorrows-pharmacist/links\\_and\\_resources/useful\\_articles/BNF](http://www.pjonline.com/tomorrows-pharmacist/links_and_resources/useful_articles/BNF)

(Accessed 24<sup>th</sup> April 2012)

Broderick W (1999). Prodigy: Practical support for clinical governance.

National Prescribing Centre Information Resource. Liverpool

- Bruner A, Kasdan ML (2001) Handwriting errors: Harmful, wasteful and preventable. The Journal of the Kentucky Medical Association; 99 (5):189-92  
Available at:  
[http://www.kyma.org/uploads/file/Patient\\_Safety/Physicians/Harmful\\_wasteful\\_and\\_preventable.pdf](http://www.kyma.org/uploads/file/Patient_Safety/Physicians/Harmful_wasteful_and_preventable.pdf)  
(Accessed 22<sup>nd</sup> March 2015)
- Bryan C, Boren SA (2008). The use and effectiveness of electronic clinical decision support tools in the ambulatory/primary care setting: a systematic review of the literature. Informatics in Primary Care; 16: 79–91
- Bryan J (2008). How ciclosporin changed attitudes towards organ transplantation. The Pharmaceutical Journal 281; 567. Available at:  
[http://www.pjonline.com/news/how\\_ciclosporin\\_changed\\_attitudes\\_towards\\_organ\\_transplantation](http://www.pjonline.com/news/how_ciclosporin_changed_attitudes_towards_organ_transplantation)  
(Accessed 13<sup>th</sup> April 2012)
- Burrill P (2003). Area Prescribing Committees: What is their role in the new NHS? The Pharmaceutical Journal; 270 (No 7241): 409
- Campbell SM, Cantrill JA, Roberts D (2000). Prescribing indicators for UK general practice: Delphi consultation study. British Medical Journal; 321: 1- 5
- Campbell SM, Cantrill JA (2001). Consensus methods in prescribing research. Journal of Clinical Pharmacy and Therapeutics; 26: 5-14
- Cantrill J A, Sibbald, Buetow S (1998) Indicators of the appropriateness of long-term prescribing in general practice in the United Kingdom: Consensus development, face and content validity, feasibility and reliability. Quality in Health Care 7: 130-135
- Chapman S (2007). Developing decision support systems for nurse prescribers. Nurse Prescribing; 5 (6): 251-255
- Chan WS, Stevenson M, McGlade K (2007). Do general practitioners change how they use the computer during consultations with a significant psychological component? Journal of Medical Informatics; 77: 534-538

- Chipman SE, Schraagen JMC, Shalin VL (2000). Chapter 1. Introduction to cognitive task analysis. Available at:  
[http://www.researchgate.net/profile/Valerie\\_Shalin/publication/228866020\\_Chapter\\_1\\_Introduction\\_to\\_Cognitive\\_Task\\_Analysis/links/00b7d529857c87dacf000000.pdf](http://www.researchgate.net/profile/Valerie_Shalin/publication/228866020_Chapter_1_Introduction_to_Cognitive_Task_Analysis/links/00b7d529857c87dacf000000.pdf)  
 (Accessed 19<sup>th</sup> November 2013)
- Christakis DA, Zimmerman FJ, Wright JA, Garrison MM, Rivara FP, Davis RL (2001). A randomised controlled trial of point of care evidence to improve the antibiotic prescribing practices for otitis media in children (2001).  
 Pediatrics;107 (2): pp. e15 (doi: 10.1542/peds.107.2.e15)  
 Available at: <http://pediatrics.aappublications.org/content/107/2/e15.full.pdf+html>  
 (Accessed 8<sup>th</sup> July 2011)
- Coiera E, Westbrook J I, Wyatt J C. The safety and quality of decision support systems. IMIA Yearbook of Medical Informatics 2006; 20-25
- Collins DJ, Nickless GD, Green CF (2004). Medication histories: does anyone know what medicines a patient should be taking? International Journal of Pharmacy Practice; 12 (4): 173 – 178
- Commercial Medicines Unit (2010) Procurement guidance for the provision of homecare delivery service of medicines to patients at home.  
 Available at:  
<https://s3-eu-west-1.amazonaws.com/media.dh.gov.uk/network/121/files/2013/08/201307-01-Procurement-guidance-for-the-provision-of-homecare-delivery-and-service-of-medicines.pdf>  
 (Accessed 7<sup>th</sup> February 2014)
- Cresswell K, Majeed A, Bates DW, Sheikh A (2012). Computerised decision support systems for health professionals: An interpretive review.  
 Informatics in Primary Care; 20: 15 - 28
- Crombie I K, Davies HTO (1996). Research in Healthcare. Design, conduct and interpretation of health services research. Chichester: Wiley
- Crowe S, Tully M P, Cantrill J A (2009). The Prescribing of specialist medicines: What factors influence GPs' decision making? Family Practice; 26: 301-308

- Davis RL, Wright J, Chalmers F, Levenson L, Brown JC, Lozano P, Christakis DA (2007). A cluster randomised clinical trial to improve prescribing patterns in ambulatory paediatrics. *PLoS Clin Trials* 2(5): e25. doi:10.1371/journal.pctr.0020025  
Available at:  
<http://www.plosclinicaltrials.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pctr.0020025&representation=PDF>  
(Accessed 8<sup>th</sup> July 2011)
- De Lusignan S, Singleton A, Wells S (2004). Lessons from the implementation of a near patient anticoagulant monitoring service in primary care. *Informatics in Primary Care*; 12(1):27-33.
- De Lusignan S (2005). The barriers to clinical coding in general practice: A literature review. *Medical Informatics and the Internet in Medicine*; 30 (2): 89 – 97.
- De Lusignan S, Chan Y (2008). The Development of Primary Care Information Technology in the United Kingdom. *Journal of Ambulatory Care Management*; 31 (3): 201–210
- Delaney BC, Fitzmaurice DA, Riaz, A, Hobbs FD (1999). Can computer decision support systems deliver improved quality on primary care? *British Medical Journal*; 319: 1-3
- Department of Health (1990). The NHS Community Care Act.  
Available at:  
[http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900019\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900019_en_1.htm)  
(Accessed 14<sup>th</sup> March 2010)
- Department of Health (1991). Responsibility for prescribing between hospitals and GPs EL (91)127; 1991  
Available at [http://www.wmrlmc.co.uk/gms2/miscellaneous/EL\\_91\\_127.pdf](http://www.wmrlmc.co.uk/gms2/miscellaneous/EL_91_127.pdf)  
(Accessed 3<sup>rd</sup> January 2011)
- Department of Health (2000). Statistical Bulletin. Prescriptions Dispensed in the Community Statistics for 1989 to 1999: England 1989 – 99. Available at:  
[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4021990.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4021990.pdf)  
(Accessed 14<sup>th</sup> March 2010)

Department of Health (2009). The NHS Quality, Innovation, Productivity and Prevention Challenge: an introduction for clinicians. Available at:  
[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\\_113807.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113807.pdf)

(Accessed 24<sup>th</sup> April 2012)

Department of Health (2010). Equity and Excellence, Liberating the NHS. Available at:  
[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\\_117794.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf)

(Accessed 16<sup>th</sup> January 2011)

Department of Health (2011). Homecare Medicines Towards a Vision for the future. Available at:  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213112/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213112/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf)

(Accessed 7<sup>th</sup> February 2014)

Department of Health (2012). Shared Care Guidelines. Available at:  
[http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH\\_4898588](http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4898588)

(Accessed 7<sup>th</sup> February 2014)

Devaney A, Lee M (2013). The use of generic immunosuppression for transplant patients: A UK perspective. *European Journal of Hospital Pharmacy*; 20: 272- 274

De Wit HAJM, Gonzalvo CM, Hurkens KPGM, Mulder WJ, Janknegt R, Verhey FR, Schols JMGA, Van der Kuy PM (2013). Development of a computer system to support medication reviews in nursing homes. *International Journal of Clinical Pharmacy*; 35: 668-672

Dreischulte T, Guthrie B (2012). High-risk prescribing and monitoring in primary care: How common is it, and how can it be improved?  
*Therapeutic Advances in Drug Safety*; 3: 175-184

Duerden M, Walley T (1999). Prescribing at the interface between primary and secondary care in the UK: Towards joint formularies? *Pharmacoeconomics*; 15 (5): 435-443

- Duerden MG, Hughes DA (2010). Generic and therapeutic substitutions in the UK: Are they a good thing? *British Journal of Clinical Pharmacology*; 70 (3): 335-341
- Duerden M, Milson D, Avery A, Smart S (2011). The Quality of GP Prescribing. The Kings Fund  
Available at: [http://www.kingsfund.org.uk/sites/files/kf/field/field\\_document/quality-gp-prescribing-gp-inquiry-research-paper-mar11.pdf](http://www.kingsfund.org.uk/sites/files/kf/field/field_document/quality-gp-prescribing-gp-inquiry-research-paper-mar11.pdf)  
(Accessed 19<sup>th</sup> August 2011)
- Duggan C, Beavon N, Bates I, Patel S (2001). Shared Care in the UK: failings of the past and lessons for the future. *The International Journal of Pharmacy Practice*; 9: 211-216
- Durieux P, Trinquart L, Colombet I, Niès J, Walton RT, Rajeswaran A, Rège-Walther M, Harvey E, Burnand B (2008). Computerised advice on drug dosage to improve prescribing practice. *Cochrane Database of Systematic Reviews*, Issue 3.  
Art. No: CD002894. DOI: 10.1002/14651858.CD002894.pub2
- Eccles M, Grimshaw J, Steen N, Parkin D, Purves I, McColl, Rousseau N (2000). The design of a randomised controlled trial to evaluate computerised decision support in primary care: The COGENT study. *Family Practice*; 17: 180-186
- Eccles M, McColl E, Steen N, Rosseau N, Grimshaw J, Parkin D, Purves I (2002). Effect of computerised evidenced based guidelines on management of asthma and angina in adults in primary care: Cluster randomised control trial. *British Medical Journal*; 325: 941-944
- Edgeworth A Coles ES (2010). An evaluation of near-patient testing of anticoagulant control in general practice. *International Journal of Health Care Quality Assurance*; 23 (4):410-21.
- Embrey D (2000) Task analysis techniques. Human Reliability Associates Ltd.
- Emery J, Walton R, Murphy M, Austoker J, Yudkin P, Chapman, C, Coulson A, Glasspool D, Fox J (2000). Computer support for interpreting family histories of breast and ovarian cancer in primary care: Comparative study with simulated cases. *British Medical Journal*; 321: 28-32
- Eslami S, Abu-Hanna A, De Keizer NF (2007a). Evaluation of out-patient computerised physician order entry systems: A systematic review.  
*Journal of the American Informatics Association*; 14: 400-406

Eslami S, De Keizer NF, Abu-Hanna A (2007b). The impact of computerised physician medication order entry in hospitalized patients: A systematic review. *International Journal of Medical Informatics*; 77: 365–376

European Medicines Agency (2012) Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices MEDDEV 2.1/6.

Available at: [http://ec.europa.eu/health/medical-devices/files/meddev/2\\_1\\_6\\_ol\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf)

(Accessed 7<sup>th</sup> February 2014)

Fernando B, Savelyich BSP, Avery A, Sheikh A, Bainbridge M, Horsefield P, Teasdale S (2004). Prescribing safety systems of general practice computer systems: evaluation using simulated test cases. *British Medical Journal*; 328: 1171-1172

Field TS, Rochon P, Lee M, Gavendo L, Baril JL, Gurwitz JH (2009). Computerised clinical decision support during medication ordering for long term care residents with renal insufficiency. *Journal of the American Informatics Association*; 16: 480-485.

Filippi A, Sabatini A, Badioli L, Samani F, Mazzaglia G, Catapano A, Cricelli C (2003). Effects of an automated electronic reminder in changing the antiplatelet drug prescribing behaviour among Italian general practitioners in diabetic patients. *Diabetes Care*; 26 (50): 1497-1500

Fitzmaurice DA, Hobbs FD, Murray ET, Bradley CP, Holder R (1996). Evaluation of a computerised decision support for oral anticoagulation management based in primary care. *British Journal of General Practice*; 46; 410: 533-535.

Fitzmaurice DA, Hobbs FDR, Delaney BC, Wilson S, McManus R (1998a). Review of computerised decision support systems for oral anticoagulation management. *British Journal of Haematology*; 102: 907-909

Fitzmaurice D, Hobbs FDR, Murray ET (1998b). Primary care anticoagulant clinic management using computerised decision support and near patient International Normalised Ratio (INR) testing: Routine data from a practice nurse–led clinic. *Family Practice*; 15 (2): 144-46



- Fitzmaurice D, Hobbs R, Murray E, Holder R, Allan T, Rose P (2000). Oral Anticoagulation Management in Primary Care with the use of Computerised decision support and near patient testing. *Archives of Internal Medicine*; 160: 2343-2348
- Fitzmaurice D, Murray E T, Gee K M, Allan T F (2001). Does the Birmingham model of oral anticoagulation management work outside of primary care work outside of trial condition? *British Journal of General Practice*; 51: 828-829
- Fitzmaurice DA, ET Murray ET, Gee KM, Allan TF, Hobbs FDR (2002). A randomised controlled trial of patient self-management of oral anticoagulation treatment compared with primary care management. *Journal of Clinical Pathology*; 55 (11): 845-849
- Fitzmaurice DA, Murray ET, McCahon D, Holder R, Raftery J P, Hussain S, Sandhar H, Hobbs FDR (2005). Self-management of oral anticoagulation: randomised trial. *British Medical Journal*; doi:10.1136/bmj.38618.580903.AE
- Franke L, Avery AJ, Groom L, Horsfield P (2000). Is there a role for computerised decision support for drug dosing in general practice? A questionnaire survey. *Journal of Clinical Pharmacy and Therapeutics*; 25: 373 – 377
- Frisher M, Short D, Bashford James (2010). Determining patient characteristics for decision analysis support systems using anonymized electronic patient records. *Health Informatics Journal*; 16 (1): 49-57
- Furness L (2000). Formularies in primary care. *Primary Care Pharmacy* 1; 2: 37-39
- Garfield S, Barber N, Walley P, Wilson A, Eliasson L (2009) Quality of medication use in primary care - mapping the problem, working to a solution: A systematic review of the literature. *BMC Medicine*; 7:50 doi:10.1186/1741-7015-7-50
- Garg AX, Adhikari, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, Sam J, Haynes RB (2005). Effects of computerised clinical decision support systems on practitioner performance and patient outcomes. *Journal of the American Informatics Association*; 293 (10): 1223-1238

- Gerada C, Tighe J (1999). A review of shared care protocols for the treatment of problem drug use in England, Scotland and Wales.  
British Journal of General Practice; 49 (439): 125-126
- Gilliam S, Steele N (2013). The Quality and Outcomes Framework - Where next?  
British Medical Journal; 346: f659
- Glasziou P, Irwig L, Mant D (2005). Monitoring in chronic disease: a rational approach.  
British Medical Journal; 330: 644-48
- Goundrey-Smith S (2006) Electronic prescribing-experience in the UK and system design issues. The Pharmaceutical Journal; 277: 485-487
- Goundrey-Smith S (2008). Principles of electronic prescribing. London: Springer
- Granby T (2005). Evidenced-based prescribing. Nurse Prescriber; 2 (2): 1-6
- Greater Manchester Medicines Management Group (2011).Background to development of Red / Amber/ Green List. Available at:  
[http://www.nyrdtc.nhs.uk/GMMM/Groups/Interface\\_Prescribing/rag/Background%20to%20development%20of%20RAG%20list.pdf](http://www.nyrdtc.nhs.uk/GMMM/Groups/Interface_Prescribing/rag/Background%20to%20development%20of%20RAG%20list.pdf)  
(Accessed 3<sup>rd</sup> January 2011): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis
- Guildford M, Ashworth M, Robotham D, Mohiddin A (2007). Achievements of metabolic targets for diabetes by English primary care practices under a new system of incentives.  
Diabetic Medicine; 24 (5): 505-511
- Guptha SH, Mittra R, Puthrasingham S, Johnson GM, Jackson SHD (2003).  
Quality in Primary Care; 11 (2): 107-116
- Haijoff S (1998). Computerised decision support systems: An overview.  
Health Informatics Journal; 4: 23- 28
- Hampson JP, Roberts R I, Morgan D A (1996). Shared care: a review of the literature.  
Family Practice; 13: 264-279

- Hancock B, Ockleford E, Windridge K (2009) An introduction to qualitative research. The NIHR Research Design Service for Yorkshire & the Humber. National Institute for Health Research  
Available at: [http://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/5\\_Introduction-to-qualitative-research-2009.pdf](http://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/5_Introduction-to-qualitative-research-2009.pdf)  
(Accessed 15<sup>th</sup> December 2013)
- Hardy A (2001). Health and Medicine in Britain since 1860. 1<sup>st</sup> ed. Basingstoke: Palgrave
- Hayward J, Thomson F, Milne H, Buckingham S, Sheikh A, Fernando B, Cresswell K, Williams R, Pinnock H (2013). Too much too late: Mixed methods multi-channel video recording study of computerised decision support and GP prescribing. Journal of the American Informatics Association; 20: e76 – e84.
- Heal SJ, Challinor N, Roome C, Gammie S, Thorne J, Wilcock M (2006). What do GPs think about joint formularies? The Pharmaceutical Journal; 276: 171-174
- Heath and Social Care Information Centre (2014). Prescriptions Dispensed in the Community, England 2003-13. Available at: <http://www.hscic.gov.uk/catalogue/PUB14414/pres-disp-com-eng-2003-13-rep.pdf>  
(Accessed 21<sup>st</sup> December 2014)
- Heller M (2007). The National Insurance Acts 1911–1947, the Approved Societies and the Prudential Assurance Company. Twentieth Century British History; 19 (1): 1-28
- Hickman M, Drummond N, Grimshaw J (1994). A taxonomy of shared care for chronic disease. Journal of Public Health Medicine; 16 (4): 447-454
- Hicks LS, Sequist TD, Ayanian JZ, Shaykevich S, Fairchild DG, Orav EJ, Bates DW (2008). Impact of computerised decision support on blood pressure management and control: a randomised controlled trial. Journal of General Internal Medicine; 23 (4): 429-441.
- Hire S, Rushforth B (2013). General practitioners' views on using a prescribing substitution application (Script-Switch®). Informatics in Primary Care; 21 (1): 1-11

- Hobbs R, Delaney B, Carson A, Kenkre J (1996). A prospective controlled trial of computerised decision support for lipid management in primary care. *Family Practice*; 13: 133-137
- Hogerzeil H (1995). Promoting rational prescribing: An international perspective. *British Journal of Clinical Pharmacology*; 39: 1-6
- Hor CP, O'Donnell JM, Murphy AW, O'Brien T, Thomas JB, Kropmans TJB (2010) General practitioners' attitudes and preparedness towards Clinical Decision Support in e-Prescribing (CDS-eP) adoption in the West of Ireland: A cross sectional study. *BMC Medical Informatics and Decision Making*; 10:2 doi:10.1186/1472-6947-10-2
- Horne R, Mailey E, Frost S, Lea R (2001). Shared Care: A qualitative study of GPs' and hospital doctors' views on prescribing specialist medicines. *British Journal of General Practice*; 51: 187-193
- Horskey J, Schiff G D, Johnston D, Mercinavage L, Bell D, Middleton B (2012). Interface design principles for usable decision support: A targeted review of best practices for clinical prescribing interventions. *Journal of Biomedical Informatics*; 45: 1202-1216
- Hunt DL, Haynes RB, Hanna SE, Smith K (1998) Effects of computer-based clinical decision support systems on physician performance and patient outcomes. A systematic review. *Journal of the American Informatics Association*; 280 (15): 1339-1346
- Ilife S, Wilcock J, Haworth D (2006). Obstacles to Shared Care for Patients with Dementia. *Family Practice*; 23: 353 - 362
- Isaac T, Weissman JS, Davis RB, Massagli M, Cyrulik, Sands DZ, Weingart SN (2009). Overrides in medication alerts in ambulatory care. *Archives of Internal Medicine*; 169 (3): 305-311;
- Jamal A, McKenzie K, Clark M ((2009). The impact of health information technology on the quality of medical and healthcare: A systematic review. *Health Informatics Management Journal*; 38 (3): 26-37

Johnson PD, Samson TMS, Booth N, Sugden B, Purves IN (2000). Using scenarios in chronic disease management guidelines for primary care.

Proceedings of the AMIA Symposium; 389–393

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244127/>

(Accessed 15th July 2011)

Johnson KB, Fitzhenry F (2006). Case Report: Activity diagrams for integrating electronic prescribing tools into clinical workflow.

Journal of the American Informatics Association; 13 (4): 391-395

Johnston ME, Langton KB, Haynes RB, Mathieu A (1994). Effects of computer-based clinical decision support systems on clinician performance and patient outcome: A critical appraisal of research. *Annals of Internal Medicine*; 120 (2):135-142

doi:10.7326/0003-4819-120-2-199401150-00007

Johnston A, Holt D (1999). Therapeutic drug monitoring of immunosuppressant drugs.

*British Journal of Clinical Pharmacology*; 47: 339 – 50

Johnston A (2011). Consensus on generic immunosuppressants in transplant patients.

The ESPIRIT Group (Efficacy and safety of prescribing in transplantation).

London: The ESPIRIT Group Ltd

Johnston A (2013). Equivalence and interchangeability of narrow therapeutic index drugs in organ transplantation.

*European Journal of Hospital Pharmacy*; 0 (1-6): doi:10.1136/ejhpharm-2012-000258

Joint Formulary Committee (2014). The British National Formulary. No 68.

London: The British Medical Association and Royal Pharmaceutical Society

Joice P, Hanna GB, Cuschieri A (1998). Errors enacted during endoscopic surgery.

A human reliability analysis. *Applied Ergonomics*; 29 (6): 409 – 414

Jones R (1986). The impact of new technology on general practice. Editorial.

*The Royal College of General Practitioners*; 26: 98-100

- Judge J, Field TS, DeFloris M, Laprino J, Rochon P, Bates DW, Gurwitz JH (2006). Prescribers' responses to alerts during medication ordering in the long term care setting. *Journal of the American Informatics Association*; 13: 385-390.
- Kaushal R, Shojania KG, Bates DW (2003). Effects of Computerised Physician Order Entry and Clinical Decision Support Systems on Medication Safety. *Archives of Internal Medicine*; 163: 1409-1416
- Kawamoto, K, Houlihan CA, Balas A, Lobach DF (2005). Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *British Medical Journal*; 765 doi: 10.1136/bmj.38398.500764.8F
- Keeling D, Baglin T, Tait C, Watson H, Perry D, Baglin C, Kitchen S, Makris M (2011). Guidelines on oral anticoagulation with warfarin (fourth edition). *British Journal of Haematology*; 154: 311-324
- Kendall H (2004). Why prescribing data are monitored. *The Pharmaceutical Journal*; 272: 21-22
- Khambh J, Barnick C (2007) Shared-care arrangements and the primary / secondary-care interface. *Prescriber*; 18 (7): 23-29
- Khan F. (2002) Using medicines wisely. The place of formulary in medicines management. *Hospital Pharmacist*; 9: 159-163
- Klntmalm G (2004) The history of organ transplantation in the Baylor health care system. *Baylor University Medical Centre Proceedings*; 17(1): 23–34 PMID: PMC1200638
- Kirwan B (1992). Human error identification in human reliability assessment. Part 2: Detailed comparison of techniques. *Applied Ergonomics*; 23 (6): 371-381
- Kirwan B (1998). Human error identification techniques for risk assessment of high risk systems. Part 1. Review and evaluation of techniques. *Applied Ergonomics*; 29 (3): 155-177

Ko Y, Abarca J, Malone DC, Dare DC, Geraets D, Houranieh A, Jones WN, Nichol WP, Schepers GP, Wilhardt M (2007). Practitioners' views on computerised drug-drug interaction alerts in the VA system. *Journal of the American Informatics Association*; 14: 56-64

Krall MA, Sittig DF (2001) Subjective assessment of usefulness and appropriate presentation mode of alerts and reminders in the outpatient setting.

Proceedings of the AMIA Symposium: 334–338

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2243416/>

(Accessed 15<sup>th</sup> July 2011)

Krall MA, Sittig DF (2002) Clinician's assessments of outpatient electronic medical record alert and reminder usability and usefulness requirements.

Proceedings of the AMIA Symposium: 400–404

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244227/>

(Accessed 15th July 2011)

Kroese W LG, Avery AJ, Savelyich BSP, Brown NS, Howard R, Hippisley-Cox J, Horsfield P (2005). Assessing the accuracy of a computerised decision support system for digoxin dosing in primary care: An observational study.

*Journal of Clinical Pharmacy and Therapeutics*; 30: 279-283

Kumarapeil P, De Lusignan S (2013). Using the computer in the clinical consultation; setting the stage, reviewing, recording, and taking actions: multi-channel video study.

*Journal of the American Informatics Association*; 20: e67–e75.

Lacey A, Luff D (2009). Qualitative data analysis. The NIHR Research Design Service for Yorkshire & the Humber. National Institute for Health Research

Available at:

[http://rds-eastmidlands.nihr.ac.uk/resources/doc\\_download/8-qualitative-data-analysis.html](http://rds-eastmidlands.nihr.ac.uk/resources/doc_download/8-qualitative-data-analysis.html)

(Accessed 3<sup>rd</sup> May 2015)

Lane R, Stanton N, Harrison D (2006). Applying hierarchical task analysis to medication administration errors. *Applied Ergonomics*; 37: 669-679

Lawrenson R, Williams T, Farmer R (1999). Clinical information for research: The use of general practice databases. *Journal of Public Health Medicine*; 21 (3): 299 – 304

- Laybourn K (2000). A Century of Labour – A History of the Labour party. 1<sup>st</sup> ed.  
Stroud: Sutton Publishing
- Le Grand A, Hogerzeil HV, Haaijer-Ruskamp M (1999). Intervention research in rational use of drugs: a review. *Health Policy and Planning*; 14, 2: 89-102
- Lester WT Grant RW, Barnett GO, Chueh HC (2005). Randomized controlled trial of an informatics-based intervention to increase statin prescription for secondary prevention of coronary disease. *Journal of General Internal Medicine*; 21: 22-29
- Levec D, Colquhoun H, O'Brien K (2010). Scoping studies: advancing the methodology  
*Implementation Science*; 5:69  
Available at: <http://www.biomedcentral.com/content/pdf/1748-5908-5-69.pdf>  
(Accessed 13<sup>th</sup> May 2015)
- Lewis G, Sharp D, Bartholomew J, Pelosi AJ (1996). Computerised assessment of common mental disorders in primary care: Effect on clinical outcome. *Family Practice*; 13 (2): 120-126
- Lloyd B (2001). A guide to making the most of ePACT.net. Guildford: A & M Publishing
- Lowensteyn I, Laseph L, Levinton C, Abrahamowicz, Steinert Y, Grover S (1998). Can computerised risk profiles help patients improve their coronary risk? [The results of the coronary health assessment study (CHAS). *Preventative Medicine*; 27: 730-737
- Lyons M, Adams S, Woloshynowych M, Vincent C (2004). Human reliability analysis in healthcare. A review of techniques.  
*International Journal of Risk and Safety in Medicine*; 16: 223 – 227
- Lyons M (2009). Towards a framework to select techniques for error prediction:  
Supporting novice users in the healthcare sector. *Applied Ergonomics*; 40: 379-395
- MacBride-Stewart, SP, Elton R, Walley T (2008). Do quality incentives change prescribing patterns in primary care? An observational study in Scotland. *Family Practice*; 25: 27-32
- Magnus D, Rodgers S, Avery AJ (2002). GPs' views on computerised drug interaction alerts: questionnaire survey. *Journal of Clinical Pharmacy and Therapeutics*; 27: 377-382



- Main C, Moxham T, Wyatt J C, Kay J, Anderson R, Stein K (2010). Computerised decision support systems in order communication for diagnostic, screening or monitoring test ordering: Systematic reviews of the effect and cost effectiveness of systems. *Health Technology Assessment*; 14: No. 48 doi: 10.3310/hta 14480
- Majeed A, Evans N, Head P (1997). Information in practice: What can PACT tell us about prescribing in general practice? *British Medical Journal*; 315: 1515-1519
- Mannan R, Murphy J, Jones M (2006). Is primary care ready to embrace e-health? A qualitative study of staff in a London primary care trust. *Informatics in primary care*; 14 (2): 121 - 131
- Marshall MN (1996). The key informant technique. *Family Practice*; 36 (1): 92-97
- Martens JD, Van der Weijden T, Severens JL, De Clercq PA, De Bruijn DP, Kester ADM, Winkens RAG (2007). The effect of computer reminders on GPs' prescribing behaviour: A cluster randomised trial. *International Journal of Medical Informatics*; 76 (Supplement): S403-S416
- Mason A, Drummond M, Hunter J, Towse A, Cooke J. (2005). An evaluation of prescribing incentive schemes: can they encourage cost-effective prescribing? *Applied Health Economics and Health Policy*, 4(2), 111-117
- Matthey F (2007). Anticoagulation monitoring and the role of general practice. *Prescriber*; 18 (22): 18-25
- McCartney P, Macdowell W, Thorogood M (1997). A randomised controlled trial of feedback to general practitioners of their prophylactic aspirin prescribing. *British Medical Journal*; 315: 35-36
- McCowan C, Neville R G, Ricketts I W, Warner F C, Hoskins G, Thomas E (2001). Lessons from a randomized controlled trial designed to evaluate computer decision support software to improve the management of asthma. *Medical Informatics and the Internet in Medicine*; 26 (3): 191-201

McInnes DK, Saltman DC, Kidd MR (2006). General Practitioners' use of computers for prescribing and electronic health records: Results from a national survey. *The Medical Journal of Australia*; 185 (2): 88-91

MHRA (2009). Drug Safety Update. Tacrolimus (Advagraf and Prograf): risk of serious medication errors. Available at: <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON088145> (Accessed 6<sup>th</sup> February 2014)

MHRA (2010). Oral tacrolimus products: measures to reduce risk of medication errors. Available at: <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON085144> (Accessed 6<sup>th</sup> February 2014)

MHRA (2012). Oral tacrolimus products: prescribe and dispense by brand name only, to minimise the risk of inadvertent switching between products, which has been associated with reports of toxicity and graft rejection. Available at: <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON155756> (Accessed 6<sup>th</sup> February 2014)

Militello LG, Hutton RJB (1998). Applied cognitive task analysis (ACTA): A practitioners' toolkit for understanding cognitive task demands. *Ergonomics*; 41(11): 1168-1641

MIMS (2014): Monthly Index of Medical Specialities (November 2014). London. Haymarket Medical Media

Millman A, Lee N, Brooke A (1995). ABC of medical computing. *Computers in General Practice* 1. *British Medical Journal*; 311 (7008): 800-802

Mitchell E, Sullivan F (2001). A descriptive feast but an evaluative famine: systematic review of published articles on primary care computing during 1980-97. *British Medical Journal*; 322 (7281): 279-82

Mitchell N, Randell, R, Foster R, Dowding D, Lattimer V, Thompson C, Cullum N, Summers R (2009). A national survey of computerised decision support systems available to nurses in England. *Journal of Nursing Management*; 17: 772-80

- Mollon B, Chong JJR, Holbrook AM, Sung M, Thabane L, Foster G (2009). BMC Medical Informatics and Decision Making; 9:11 doi:10.1186/1472-6947-9-11
- Montgomery AA, Fahey T, Peters T J, MacIntosh C, Sharp DJ (2000). Evaluation of computer based decision support systems and risk chart for management of hypertension in primary care: Randomised controlled trial. British Medical Journal; 320: 686-690
- Montori VM, Dinneen SF, Gorman CA, Zimmerman BR, Rizza RA, Bjornsen SS, Green EM, Bryant SC, Smith SA (2002). The impact of planned care and a diabetes electronic management system on community-based diabetes care. Diabetes Care; 25 (11): 1952-1957
- Morris AH (2002). Decision support and safety of clinical environments. Quality and Safety in Healthcare; 11: 69-75
- Morris L, Dumville J, Campbell LM, Sullivan F (2003). A survey of computer use in Scottish primary care: general practitioners are no longer technophobic but other primary care staff need better computer access Informatics in Primary Care; 11 (1): 5-11
- Morris CJ, Savelyich BSP, Avery AJ, Cantrill JA, Sheikh A (2005). Patient safety features of clinical computer systems: Questionnaire survey of GP views. Quality and Safety in Healthcare; 14: 164-68
- Moxey A, Robertson J, Newby D, Hains I, Williamson M, Pearson SA (2010). Computerised clinical decision support for prescribing: Provision does not guarantee uptake. Journal of the American Informatics Association; 17: 25-33
- National Audit Office (1994). A Prescription for Improvement. London: The Stationary Office.
- National Audit Office (2003). Primary Care Prescribing – A Bulletin for Primary Care Trusts. London: The Stationary Office
- National Audit Office (2007). Prescribing Costs in Primary Care. London: The Stationary Office
- National Institute of Clinical Excellence (2004). Immunosuppressive therapy for renal transplantation in adults. Technology Appraisal Guidance. No85. London

National Institute of Clinical Excellence (2005). Press Release. NICE assess the feasibility of evaluating computerised decision support systems.

Search of website: <https://www.nice.org.uk/>

(Accessed 5<sup>th</sup> December 2011): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis

National Institute of Clinical Excellence (2009). Shared learning in hypertension.

Available at <https://www.nice.org.uk/proxy/?sourceurl=http://www.nice.org.uk/sharedlearning>

(Accessed 5<sup>th</sup> December 2011)

National Institute of Clinical Excellence (2013) NICE Accreditation.

Available at <http://www.nice.org.uk/aboutnice/accreditation/index.jsp>

(Accessed 7<sup>th</sup> February 2014)

National Patient Safety Association (2006). Risk assessment programme overview.

Available at: <http://www.nrls.npsa.nhs.uk/resources/>

(Accessed 5<sup>th</sup> April 2015)

National Patient Safety Association (2010). National Reporting and Learning Service.

Lessons from high hazard industries for healthcare.

Available at: <http://www.nrls.npsa.nhs.uk/resources/>

(Accessed 24<sup>th</sup> November 2013)

National Patient Safety Agency (2011). Response to a freedom of information (FOI) request made by e-mail. Received by Narinder Chana 2<sup>nd</sup> March 2011

National Prescribing Centre (1999) Drug interactions in general practice. Meref Bulletin:

Volume 10. No 4. Liverpool

National Prescribing Centre (2000). Area Prescribing Committees – Monitoring effectiveness in the modern NHS, a guide to good practice. Liverpool

National Prescribing Centre (2007a) Quality in Prescribing. Available at:

[http://www.npc.nhs.uk/improving\\_safety/improving\\_quality/resources/5mg\\_qualityprescribing.pdf](http://www.npc.nhs.uk/improving_safety/improving_quality/resources/5mg_qualityprescribing.pdf)

(Accessed 26<sup>th</sup> April 2012)

National Prescribing Centre (2007b). Managing Medicines across the Health Economy. Liverpool

National Prescribing Centre (2012). Key therapeutic topics. Medicines management options for local implementation. Version 4.2. Available at:

[http://www.npc.nhs.uk/qipp/resources/Key\\_therapeutic\\_topics\\_Medicines\\_Management\\_for\\_local\\_implementation\\_April\\_2012.pdf](http://www.npc.nhs.uk/qipp/resources/Key_therapeutic_topics_Medicines_Management_for_local_implementation_April_2012.pdf)

(Accessed 20<sup>th</sup> April 2012)

NHS Employers and the British Medical Association (2009).

Quality and Outcomes Framework guidance for GMS contract 2009/10. London

NHS Employers (2009). National Enhanced Service Anticoagulation Monitoring.

Available at:

[http://www.nhsemployers.org/~media/Employers/Documents/Primary%20care%20contracts/GMS/Archived%20GMS%20contract%20Changes%202004-2010/2003-2004/nhs\\_anti\\_coagulation\\_cd\\_130209.pdf](http://www.nhsemployers.org/~media/Employers/Documents/Primary%20care%20contracts/GMS/Archived%20GMS%20contract%20Changes%202004-2010/2003-2004/nhs_anti_coagulation_cd_130209.pdf)

(Accessed 26<sup>th</sup> July 2015)

NHS Blood and Transplant (2013). Organ Donation. Available at:

[http://www.organdonation.nhs.uk/statistics/downloads/united\\_kingdom\\_sep13.pdf](http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_sep13.pdf)

(Accessed 27<sup>th</sup> October 2013)

NHS England (2013) Green light for £260 million technology fund to make the NHS safer

Available at <http://www.england.nhs.uk/2013/05/22/tech-fund/>

(Accessed 7<sup>th</sup> February 2014)

NHS England (2014). Securing excellence in GP IT services. Available at:

<http://www.england.nhs.uk/wp-content/uploads/2014/04/gp-it-nhs-op-model.pdf>

(Accessed 26<sup>th</sup> April 2015).

NHS Prescription Services (2012) Available at:

<http://www.nhsbsa.nhs.uk/PrescriptionServices/3230.aspx>

(Accessed throughout 2011, last accessed 3<sup>rd</sup> January 2012)

- NHS Specialist Commissioning Transition (2012). Kidney care commissioning. Opportunities for driving improvements in quality and productivity in kidney care services. A transitional plan for 2012-2013. Available at:  
[http://www.kidney.org.uk/documentlibrary/Kidney-Care\\_Commissioning\\_140512.pdf](http://www.kidney.org.uk/documentlibrary/Kidney-Care_Commissioning_140512.pdf)  
 (Accessed 7<sup>th</sup> February 2014)
- O’Cathian A, Webber E, Nicholl J, Munro J, Knowles E (2003) NHS Direct: consistency of triage outcomes. *Emergency Medical Journal*; 20:289-292
- Oppenheim A (1992). *Questionnaire Design, Interviewing and Attitude Measurement*. Kings Lynn: Biddles Ltd
- Oppenkowski TP, Murray ET, Sandhar H, Fitzmaurice DA (2003). External quality assessment for warfarin dosing using computerised decision support software. *Journal of Clinical Pathology*; 56: 605-607
- Parish PA (1973). Drug prescribing, a concern for all. *Journal of the Royal Society for Health*; 4: 213–7
- Parish P A (1976) Prescribing: The role of the Department of Health and Social Security. *The Journal of the Royal College of General Practice*; 26 (Supplement 1): 5-10
- Pearson SA, Moxey A, Robertson J, Hains I, Williamson M, Reeve J, Newby D (2009). Do computerised clinical decision support systems for prescribing change practice? A systematic review of the literature (1990-2007). *BMC Health Services Research*; 9:154 doi:10.1186/1472-6963-9-154
- Pell JP, McIver B, Stuart P, Malone DNS, Alcock J (1993). Comparison of anticoagulant control among patients attending general practice and a hospital anticoagulant clinic. *British Journal of General Practice*; 43: 152-154
- Petty D, Lloyd D (2008). Can cheaper generic statins achieve national cholesterol lowering targets? *Journal of Health Services Research and Policy*; 13, 2: 99-102
- Phillips S, Cox J (2005). Progress report on decision support systems. NICE Project Team. Website search <https://www.nice.org.uk/>  
 (Accessed 5<sup>th</sup> December 2011)

- Phipps D, Meakin GH, Beatty PCW, Nsoedo C, Parker D (2008). Human factors in anaesthetic practice. Insights from a task analysis.  
British Journal of Anaesthesia; 100 (30): 333-43
- Phipps DL, Meakin GH, Beatty PCW (2011). Extending hierarchical task analysis to identify cognitive demands and information design requirements. Applied Ergonomics; 42: 741-748.
- Picton C (2008). What you need to know about the drugs bill and medicines management. A guide for all NHS managers. Liverpool. The National Prescribing Centre.
- Picton C, Wright C (2013). Medicines Optimisation: Helping patients to make the most of medicines. Royal Pharmaceutical Society.  
Available at: <http://www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf>  
(Accessed 6<sup>th</sup> September 2015)
- Poels PJP, Schermer TRJ, Schellekens DPA, Akkermans RP, de Vries Robbe PF, Kaplan A, Bottema BJAM, van Weel C (2008). Impact of a spirometry expert system on general practitioners' decision making. European Respiratory Journal; 31: 84 – 92
- Pope C, Ziebland S, Mays N (2000). Qualitative research in health care: Analysing qualitative data. British Medical Journal; 320: 114-116
- Primary Care Contracting (2006). Developing General Practice in Anytown PCT through a Balanced Scorecard Approach. Available at:  
[http://www.pcc.nhs.uk/uploads/balanced\\_score\\_card\\_dec\\_06/balanced\\_scorecard\\_final.pdf](http://www.pcc.nhs.uk/uploads/balanced_score_card_dec_06/balanced_scorecard_final.pdf)  
(Accessed 30<sup>th</sup> June 2010)
- Protti D (2005). The Benefits of Computer Technology Can Only Be Realised When Systems of Work Are Changed. Available at:  
<http://www.connectingforhealth.nhs.uk/newsroom/worldview/protti6>  
(Accessed 30<sup>th</sup> June 2010)
- Purves I (1996). Editorial. The paperless general practice. British Medical Journal; 312: 1112  
Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2350647/pdf/bmj00540-0006.pdf>  
(Accessed 8<sup>th</sup> March 2015)

Purves I, Sowerby M (1996): Prodigy Interim Report.

Journal of Informatics in Primary Care; 2: 8

Available at <http://www.primis.nhs.uk/informatics/sep96/sep.2htm>

(Accessed 30<sup>th</sup> June 2010): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis

Purves I N, Sugden B, Booth N, Sowerby M (1999). The PRODIGY Project - the Iterative Development of the Release One Model.

Available at:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2232876/pdf/procamiasymp00004-0396.pdf>

(Accessed 30<sup>th</sup> June 2010)

Rago L, Santoso B (2008) Drug Regulation: History, Present and Future.

Available at:

[http://www.who.int/medicines/technical\\_briefing/tbs/Drug\\_Regulation\\_History\\_Present\\_Future.pdf](http://www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf)

(Accessed 26<sup>th</sup> April 2012)

Ritchie J, Spencer, L (1994). Qualitative data analysis for applied policy research.

In: Bryman A, Burgess R, editors. Analysing qualitative, London: Routledge

Rivett G (2012) National Health Service History 1958-1967 - The renaissance of general practice and the hospitals. Available at: [http://www.nhshistory.net/chapter\\_2.htm](http://www.nhshistory.net/chapter_2.htm)

(Accessed 26<sup>th</sup> April 2012)

Robinson GM (2004). Using a clinical decision-making support tool to enhance practice.

Nursing Times; 100 (40): 32-34

Available at:

<http://www.nursingtimes.net/Journals/2013/02/15/o/t/p/041005Using-a-clinical-decision-making-support-tool-to-enhance-practice.pdf>

(Accessed 11<sup>th</sup> April 2011)

Robertson J, Moxey AJ, Newby DA, Gillies MB, Williamson M, Pearson S (2011). Electronic information and clinical decision support for prescribing: state of play in Australian general practice. Family Practice; 28: 93-101



- Roland M, Campbell S, Bailey N, Whalley D, Sibbald B (2005), Financial incentives to improve the quality of primary care in the UK: predicting the consequence of change. *Primary Health Care Research and Development*; 7: 18-26
- Roland M, Guthrie B, Thomé DC (2012). Primary Medical Care in the United Kingdom. *Journal of the American Board of Family Medicine*; 25: S6 –11.
- Roshanov PS, Fernandes N, Wilczynski JM, Hemens BJ, You JY, Handler SM, Nieu R, Souza NM, Beyene J, Van Spall HGC, Garg AX, Haynes RB (2013). Features of effective computerised clinical decision support systems: Mega-regression of 162 randomised trials. *British Medical Journal*; 346: f657 doi: 10.1136/bmj.f657
- Rosseau N, McColl E, Newton J, Grimshaw J, Eccles M (2003). Practice based longitudinal, qualitative interview study of computerised evidence based guidelines in primary care. *British Medical Journal*; 326; 314
- Rossi RA, Every NR (1997). A computerised intervention to decrease the use of calcium channel blockers in hypertension. *Journal of General Internal Medicine*; 12: 672-678
- Roumie CL, Elasy TA, Greevy R, Griffin MR, Liu X, Stone WJ, Wallston K, Dittus RS, Alvarez V, Cobb J, Speroff T (2006). Improving blood pressure through provider education, provider alerts and patient education. *Annals of Internal Medicine*; 145: 165-175
- Ryan M, Yule B (1993). The way to economic prescribing. *Health Policy*; 25(1-2):25-38.
- Sackett et al (1996) Evidence based medicine: what it is and what it isn't  
*British Medical Journal*; 312: 71-72
- Salt N, Parkes E, Scammell A. (2005) GPs' perceptions of the management of ADHD in primary care: A study of Wandsworth GPs.  
*Primary Health Care Research and Development*; 6: 162-171
- Samore M, Bateman K, Alder SC, Hannah E, Donnelly S, Stoddard GJ, Haddadin B, Rubin MA, Williamson J, Stuts B, Rupper R, Stevenson K (2005). Clinical decision support and appropriateness of antimicrobial prescribing. *Journal of the American Informatics Association*; 294 (18): 2305-2314
- Savage SP, Atkinson R (2001). Public Policy under Blair. 1<sup>st</sup> ed. Basingstoke: Palgrave

Schedlbauer A, Prasad V, Mulvaney C, Phansalkar, Stanton W, Bates DW, Avery AJ (2009) What evidence supports the use of computerised alerts and prompts to improve clinicians prescribing behaviour?

Journal of the American Informatics Association; 16 (4): 531-538

Sequist TD, Gandhi TK, Karson AS, Fikio JM, Bugbee D, Sperling M. Cook F, Orav EJ, Fairchild DG, Vates DW (2005). A randomised trial of electronic clinical reminders to improve quality of care for diabetes and coronary heart disease.

Journal of the American Informatics Association; 12 (4): 431-437

Shaver EF, Braun CC (2008). What is Human Factors and Ergonomics? Available at:

<http://www.benchmarkrs.com/uploads/What-is-Human-Factors-and-Ergonomics.pdf>

(Accessed 24<sup>th</sup> November 2013)

Shepherd A (2001). Hierarchical Task Analysis. 1<sup>st</sup> ed. Padstow: Taylor and Francis

Shiach C, Campbell B, Poller L, Keown M, Chauhan N (2002). Reliability of point of care prothombin time testing in a community clinic: A randomized crossover comparison with laboratory testing. British Journal of Haematology; 119: 370-375

Short D, Norwood J (2003). Why is high-tech healthcare at home purchasing underdeveloped and what could be done to improve it? Health Service Management Research; 16: 127-135

Short D, Frischer M, Basford J, Ashcroft D (2003). Why are eligible patients not prescribed aspirin in primary care? A qualitative study indicating measures for improvement.

BMC Family Practice; 4: 9

Short D, Frischer M, Bashford J (2004). Barriers to the adoption of computerised decision support systems in general practice consultations: A qualitative study of GP's perspectives.

International Journal of Medical Informatics; 73: 357-362

Shortliffe E (1987). Computer programs to support clinical decision making.

Journal of the American Informatics Association; 258; 61-66

- Sibbald B, Wilkie P, Raftery J, Anderson S, Freeling S (1992). Prescribing at the hospital-general practice interface II: Impact of hospital outpatient dispensing policies in England on general practitioners and hospital consultants. *British Medical Journal*; 304: 31-34
- Silcock J, Raynor D K T, Petty D (2003). The organisation and development of primary care pharmacy in the United Kingdom. *Health Policy*; 67: 207-214
- Simister K (2000). The role of national agencies in the managed introduction of new drugs for arthritis. *Annals of the Rheumatic Diseases*; 59: i38-i40
- Simon C (2009). From generalism to speciality: A short history of general practice. *InnoVAIT*; 2 (1): 2-9
- Sintchenko V, Magabri F, Tipper S (2007). Are we measuring the right end points? Variables that affect the impact of computerised decision support on patient outcomes: A systematic review. *Medical Informatics and the Internet in Medicine*; 32 (3): 225-240
- Sittig DF, Krall MA, Dykstra RH, Russell A, Chin HL (2006). A survey of factors affecting clinician acceptance of clinical decision support. *BMC Medical Informatics and Decision Making*; 6 (6) doi:10.1186/1472-6947-6-6
- Slight SP, Howard R, Maisoon G, Barber N, Franklin BD, Avery AJ (2013). The causes of prescribing errors in English general practices: a qualitative study. *British Journal of General Practice*; e713 – e719  
Available at: <http://bjgp.org/content/bjgp/63/615/e713.full.pdf>  
(Accessed 24<sup>th</sup> August 2015)
- Smith P, York N. (2004) Quality Incentives: The case of UK General Practitioners. *Health Affairs*. 23, 3; 112-118. Available at: <http://healthaffairs.org/cgi/content/full/23/3/112>  
(Accessed 23<sup>rd</sup> April 2010)
- Smith S M, Allwright S, O'Dowd T (2009). Effectiveness of shared care across the interface between primary and specialty *Cochrane Database Systematic Reviews*; 16 (3): CD002894
- Snowden H, Marriott S (2003). Developing a local shared care protocol for managing people with psychotic illness in primary care. *Psychiatric Bulletin*; 27: 261-266
- Spradley JP (1979). *The Ethnographic Interview*. Belmont: Wadsworth Group

- Stanton N (2006). Hierarchical task analysis: Developments, applications and extensions. *Applied Ergonomics*; 37: 55-79
- Steele N, Maisey S, Clark A, Fleetcroft R, Howe A (2007). Quality of clinical primary care and targeted incentive payments: An observational study. *British Journal of General Practice*; 57: 449-454
- Stephens M (2005). *Strategic Medicines Management*. London: The Pharmaceutical Press
- Sugden B, Wilson R, Cornford J (2008). Reconfiguring the health supplier market: Changing relationships in the primary care supplier market in England. *Health Informatics Journal*; 14 (2): 113-124
- Sullivan F, Mitchell E (1995). Has general practitioner computing made a difference to patient care? A systematic review of published reports. *British Medical Journal*; 311: 848-852
- Sweidan M, Reeve JF, Brien JE, Jayasuriya P, Martin JH, Vernon GM (2009). Quality of drug interaction alerts in prescribing and dispensing software. *The Medical Journal of Australia*; 109 (5) 251-254
- Sweidan M, Williamson M, Reeve JF, Harvey K, O'Neil J, Schattner P, Snowden T (2010). Identification of features of electronic prescribing systems to support quality and safety in primary care using a modified Delphi process. *BMC Medical Informatics and Decision Making*; 10:21 doi:10.1186/1472-6947-10-21
- Tamblyn R, Huang A, Perreault R, Jacques A, Roy D, Hanley J, McLeod P, Laprise R (2003). The medical office of the 1st century (MOXXI): Effectiveness of computerised decision making support in reducing inappropriate prescribing in primary care. *Canadian Association Medical Journal*; 169 (6): 549-556
- Taylor RJ (1977). General Practitioner Prescribing. *Journal of the Royal College of General Practitioners*.; 27: 79-82
- Taylor RJ (1978). Towards better prescribing. *Journal of the Royal College of General Practitioners*; 28: 263-270

The Kings Fund (2011) Improving the quality of care in general practice.

Report of an independent inquiry commissioned by The King's Fund. Available at:

[http://www.kingsfund.org.uk/publications/gp\\_inquiry\\_report.html](http://www.kingsfund.org.uk/publications/gp_inquiry_report.html)

(Accessed 2<sup>nd</sup> June 2012)

Thiru K, Hassey A, Sullivan F (2003). Systematic review of scope and quality of electronic patient record data in primary care. *British Medical Journal*; 326: 1070-1074

Thistlethwaite JE, Ajjawi R, Aslani P (2010). The decision to prescribe: Influences and choice. *InnoVAIT*; 3 (4): 237-243

Thomas HV, Lewis G, Watson M, Bell T, Lyons I, Lloyd K, Wich S, Sharp D (2004). Computerised patient specific guidelines for management of common mental disorders in primary care: A randomised controlled trial. *British Journal of General Practice*; 54: 832-837

Thomson M (2007). The BNF and BNFC. Drug Information design for your pocket and desktop. *The Pharmaceutical Journal*; 279: 344-345

Thornett AM (2001). Computer Decision support systems in general practice. *International Journal of Information Management*; 21, 1: 39 – 47

Tierney WM, Overhage JM, Murray MM, Harris LE, Zhou X, Eckert GJ, Smith FE, Nienaber N, McDonald CJ, Wolinsky FD (2003). Effects of computerised guidelines for managing heart disease in primary care; *Journal of General Internal Medicine*; 18: 967-976

Tierney WM, Overhage JM, Murray MM, Harris LE, Zhou X, Eckert GJ, Smith FE, Nienaber N, McDonald CJ, Wolinsky FD (2005). Can computer-generated evidence-based management of asthma and chronic obstructive pulmonary disease? A randomised controlled trial. *Health Services Research*; 40 (2): 477-497

Toth-Pal E, Wardh I, Strender L, Nilsson G (2008). A guideline based computerised decision support system (CDSS) to influence general practitioners management of chronic heart failure. *Informatics in Primary Care*; 16: 29-39

Treharne Jones R, Sullivan M, Barrett D (2005). INRstar: Computerised decision support software for anticoagulation management in primary care. *Informatics in Primary Care*; 13: 215-221

- Tsimtsoui Z, Ashworth M, Jones R (2009). Variations in anxiolytic and hypnotic prescribing by GPs: A cross sectional analysis using data from the UK Quality and Outcomes Framework. *British Journal of General Practice*; 59, 563: 191-198
- Vadher B, Patterson DLH, Leaning M (1997). Evaluation of a decision support system for initiation and control of oral anticoagulation in a randomised trial. *British Medical Journal*; 314: 1252-1256
- Van Schaik P, Flynn D, Wersch AV, Douglass A, Cann P (2004). The acceptance of computerised decision support: A preliminary investigation. *Behaviour and Information Technology*; 23 (5): 321-326
- Van der Sijs H, Aarts R, Vulto A, Berg M (2006). Overriding of drug safety alerts in computerised physician order entry. *Journal of the American Informatics Association*; 13: 138-147
- Wade OL (2003). The British National Formulary – Memoirs of a former chairman. *The Pharmaceutical Journal*; 279: 278-281
- Walton RT, Gierl C, Yudkin P, Mistry H, Vessey MP, Fox J (1998). Evaluation for computer support in prescribing (CAPSULE) using simulated cases. *British Medical Journal*; 315: 791-795
- Walton RT, Dovey S, Harvey E, Freemantle N (1999). Computer support for determining drug dose: Systematic review and meta-analysis. *British Medical Journal*; 318: 984-990
- Walton RT, Harvey E, Dovey S, Freemantle N (2001). Computerised advice on drug dosage to improve prescribing practice. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No: CD002894. DOI: 10.1002/14651858.CD002894
- Watson CJE, Dark JH (2012). Organ transplantation: historical perspective and current practice. *British Journal of Anaesthesia*; 108 (S1): i29–i42
- Weingart SN, Toth M, Sands DZ, Aronson MD, Davis R, Phillips RS (2003). Physicians' decisions to override computerised drug alerts in primary care. *Arch Intern Med*; 163: 2625-2631

Wilson B J, Torrance N, Miollison J, Wordsworth S, Gray J R, Haites N E, Grant A, Campbell M K, Miedzybrodzka Z, Clarke A, Watson M S, Douglas A (2005). Improving the referral process for familial breast cancer genetic counselling: Findings of three randomised controlled trials of two interventions.

Executive Summary. Health Technology Assessment; 9: No 3

Available at: <http://www.hta.nhs.uk/pdfexecs/summ903.pdf>

(Accessed 2<sup>nd</sup> November 2012): Material no longer accessible (26<sup>th</sup> July 2015) but a printout is available on request from the author of this thesis

World Health Organisation (2002). Promoting rational use of medicines: core components.

Available at: <http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf>

(Accessed 14th June 2010)

Wyatt J (1991a). Use and sources of medical knowledge. The Lancet; 338: 1368-1373

Wyatt J (1991b): Computer based knowledge systems. The Lancet; 338: 1431-1436

Wyatt J, Spiegelhalter D (1992). Field trials of medical decision aids: potential problems and solutions. Proceedings of the fifteenth annual symposium on computer applications in medical care. American Medical Informatics Association; 3-7

Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2247484/pdf/procascamc00004-0028.pdf>

(Accessed 17<sup>th</sup> March 2011)

Yourman L, Concato J, Agostini J (2008). Use of computer decision support interventions to improve medication prescribing in older adults: A systematic review. The American Journal of Geriatric Pharmacotherapy; 6 (2): 119-129

Xiao L, Cousins G, Courtney B, Hederan L, Fahey, T, Dimitrov BD (2011). Developing an electronic health record (EHR) for methadone treatment recording and decision support. BMC Medical Informatics and Decision Making; 11:5 doi: 10.1186/1472-6947-11-5

## Appendix 3.1

### INTERVIEW SCHEDULE

**Exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.**

#### GP VERSION

### Introduction

Thank you for agreeing to participate in this study which aims to explore the views, perceptions and experiences of individuals in the use of CDSS. I will be grateful if you could confirm that you have seen and read the information sheet and that you have read and signed the consent form. During the interview I will be taking written notes but will also be using an audio tape recorder to help me write up a transcript. The recording will be destroyed after the completion of my doctorate. Please explain things to me as if I am one of your colleagues. I may ask you for clarification and examples of the topics discussed. Feel free to stop me if you have any questions or need anything explained.

### Background

CDSS can function as either “active” whereby it interacts within a host clinical system or “passive” whereby the end user decides when and where to use it. Firstly we will be discussing your use of CDSS in your practice

### Evaluation of CDSS

Now I'd like to discuss your views and perceptions of CDSS in terms of likes and dislikes as well as your opinion of the advantages of systems and disadvantages of different systems.

### Consider the following questions and scenarios:

- Describe your experience of using computers in general practice and using electronic health records.
- What are your views and experience of “active” CDSS where software interacts with the GP practice computer system at the point of prescribing or using other areas of electronic health records?
- What are your views and experience of “passive” CDSS where the user decides when or where to access?



- Which CDSS have you used please give details
- Which type of CDSS do you prefer and why?
- In your opinion what are the advantages that CDSS provides during consultations. Please give examples
- Are there any advantages for CDSS in other areas of your work in general practice?
- In your opinion what are the disadvantages of CDSS?
- Are there aspects of prescribing or clinical areas where you find CDSS particularly helpful and why?
- In your opinion what does CDSS improve the quality of care or medical advice that you provide? Please give examples
- Have you any experiences where CDSS has had any adverse effect on patient care or clinical outcomes and if so what happened?
- Describe any other resources, other than CDSS, which you use to aid prescribing and your work in general practice. What advantages and if any do they confer and what are they?
- Are aware of any CDSS in development, please provide details on patients groups, medicines etc.?

### Shared care protocols, Specialist Drugs, and CDSS

In the UK there has been a growing trend for some specialised hospital initiated treatments to be managed within primary care. Often this is within so called “shared care arrangements” using “shared care protocols”. In addition I will be asking you about your views and experiences when dealing with requests from hospital clinicians to prescribe specialist drugs, and using shared care protocols.

In England during 2010 / 11 over 1.6 million prescription items were issued by GPs for specialist drugs at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill. Of this £65 million (26.3%) was spent on the immunosuppressant drugs **ciclosporin, mycophenolate, sirolimus and tacrolimus**. In addition these four drugs accounted for 31.7% of all specialist drugs prescribed, **making these the most frequently issued by GPs in primary care**. Shared care protocols are designed to support the management of specialist drugs that are initiated by secondary care clinicians and then passed on to GPs to prescribe and monitor in primary care.

- Are you familiar with shared care protocols and if so describe your experience of using them?
- Have you ever been asked to comment on or been involved in developing a shared care protocol and if you have please provide some details?

As a potential area for development this study will be looking to explore if CDSS could have a role in helping GPs prescribe and manage specialist drugs in primary care. Based on your experience of general practice, primary care and taking account of current NHS policy I will like to discuss with you the following:

- Describe your experiences of prescribing specialist drugs in primary care
- Which specialist drugs have you prescribed in the past or are currently prescribing and were you able to use shared care protocols for these drugs?
- Have you experienced any problems or difficulties in prescribing specialist drugs, and if so how could they have been avoided?
- What experience do you have in the prescribing and management of patients with any of the four immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus?
- What do you think of the idea of a CDSS; specifically designed to support the prescribing of specialist drugs?
- If such a CDSS was developed, what do you think would be the advantages and disadvantages for GPs?
- What do you think are the disadvantages of using a CDSS to support the prescribing of specialist drugs?
- Describe how you think such a CDSS would best operate including any specific characteristics or features?

Finally one last question; in your opinion should funding come from any or all of the following to develop and or implement such a CDSS: NHS, CDSS suppliers, GP practice computer suppliers or GPs?

## Conclusion

Thank you for your time and I am very grateful that you have given me an insight into your views and perceptions of CDSS and its potential role in supporting the prescribing of specialist drugs. I would like to remind you that if you wish to withdraw from the study you will need to inform the research team within 48 hours.

## Appendix 3.2

### INTERVIEW SCHEDULE

**Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice.**

#### SECONDARY CARE CLINICIAN VERSION

### Introduction

Thank you for agreeing to participate in this study which aims to explore the views, perceptions and experiences of individuals in the use of CDSS. I will be grateful if you could confirm that you have seen and read the information sheet and that you have read and signed the consent form. During the interview I will be taking written notes but will also be using an audio tape recorder to help me write up a transcript. The recording will be destroyed after the completion of my doctorate. Please explain things to me as if I am one of your colleagues. I may ask you for clarification and examples of the topics discussed. Feel free to stop me if you have any questions or need anything explained.

### Background

Specialist drugs have been defined as those that have significant pharmacological complexity and or rarity of use which make prescribing them in community relatively uncommon. In addition patients receiving these drugs may require particular complex monitoring requiring specialist knowledge for interpretation and management. Guidance from the NHS Management Executive issued in 1991 outlined core principles and responsibilities associated with prescribing particularly with the transfer of treatment between secondary and primary care. Where this involves new or rarely prescribed treatments, including unlicensed drugs, shared care arrangements should be proposed in the form of a “protocol” outlining responsibilities for both hospital and primary care clinicians.

In recent years there has been a growing trend for some specialised hospital initiated treatments to be managed within primary care, attributed to patient convenience, better risk management, a reduction in secondary care workload (e.g. out-patient appointments) and the transfer out of prescribing expenditure. In England during 2010 / 11 over 1.6 million prescription items were issued by GPs for specialist drugs at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill. Of this £65 million (26.3%) was spent on the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus.

In addition these four drugs accounted for 31.7% of all specialist drugs prescribed, making these the most frequently issued by GPs in primary care.

Firstly we will be discussing some background information about your experience in the use of specialist drugs and we will consider the following questions and scenarios;

- Describe some of the challenges you have experienced with regard to prescribing, monitoring and therapeutic management of these drugs?
- What are your experiences of the transfer of care between secondary care and primary care? Please comment on the advantages, disadvantages and specific interface issues related to these drugs?
- What are your experiences of using of shared care protocols? Please comment on your experience on the writing, design of shared care protocols
- What are your experiences of using of shared care protocols to enable GPs to manage patients on specialist drugs?
- Based on your experience which individuals are normally involved in the development of a shared care protocol?
- Would this involve GPs or other primary care based clinicians?
- What are the barriers and enablers to developing shared care protocols for the prescribing and monitoring of specialist drugs by GPs?

### **Potential Area for CDSS Development**

The last 30 years has seen the emergence of CDSS to aid diagnosis, dose calculations and more recently to support computerised or electronic prescribing via alerts to warnings on drug interactions, allergies and contraindications. CDSS can function as either “active” whereby it interacts within a host clinical system or “passive” whereby the end user decides when and where to use it. As a potential area for development this study will be looking to explore if CDSS could have a role in helping GPs prescribe and manage specialist drugs in primary care. Based on your experience of the NHS and the use of specialist drugs we will discuss this area considering a number of aspects to include the following questions and scenarios:

- What are your views on the feasibility of CDSS supporting the prescribing specialist drugs compared to current arrangements including using shared care protocols?
- If a CDSS were to be developed for use in primary care by GPs what key features and functionality standards do you feel would be important in relation to the prescribing and monitoring of specialist drugs and why?

- What reservations or concerns (if any) do you have regarding the development of a CDSS to support the prescribing of specialist drugs by GPs?

## **Conclusion**

Thank you for your time and I am very grateful that you have given me an insight into your experience of specialist drugs and your views on the potential use of CDSS to support prescribing in general practice. I would like to remind you that if you wish to withdraw from the study you will need to inform the research team within 48 hours.

### Appendix 3.3

#### INTERVIEW SCHEDULE

**Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice.**

#### NHS MANAGEMENT VERSION

#### Introduction

Thank you for agreeing to participate in this study which aims to explore the views, perceptions and experiences of individuals in the use of CDSS. I will be grateful if you could confirm that you have seen and read the information sheet and that you have read and signed the consent form. During the interview I will be taking written notes but will also be using an audio tape recorder to help me write up a transcript. The recording will be destroyed after the completion of my doctorate. Please explain things to me as if I am one of your colleagues. I may ask you for clarification and examples of the topics discussed. Feel free to stop me if you have any questions or need anything explained.

#### Background

The last 30 years has seen the emergence of CDSS to aid diagnosis, dose calculations and more recently to support computerised or electronic prescribing via alerts to warnings on drug interactions, allergies and contraindications. CDSS can function as either “active” whereby it interacts within a host clinical system or “passive” whereby the end user decides when and where it is used. Firstly we will be discussing your experience in the NHS of information technology and systems to aid electronic or computerised prescribing.

- What is your current (and / or previous) experience of information technology in the NHS?
- Explain the key components that clinical system suppliers provide in relation to prescribing support and current contractual arrangements with the NHS including specific requirements for CDSS
- What are the contractual requirements for commercial organisations with regards integration with NHS clinical systems such as GP practice computer systems

### CDSS: Enablers and Barriers

CDSS is widely available within primary care settings in the UK as computers are now common place in GP practices. The actual use and perceptions of those using CDSS may be influenced by a number of factors. Based on your knowledge and experience in this area we will be discussing this further. We will explore the following aspects:

- What are your experiences with regards to actual usage and acceptance of CDSS from either end users or purchasers (NHS)?
- How are either end users or purchasers involved in the on-going management and / or development of CDSS?
- What barriers are there to the implementation of CDSS within primary care?
- How can these barriers be avoided or removed?

### Potential Area for CDSS Development

In England during 2010 / 11 over 1.6 million prescription items were issued by GPs for specialist drugs at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill. Of this £65 million (26.3%) was spent on the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus. In addition these four drugs accounted for 31.7% of all specialist drugs prescribed, making these the **most frequently issued by GPs in primary care**. As a potential area for development this study will be looking to explore if CDSS could have a role in helping GPs prescribe and manage specialist drugs in primary care. Based on your experience of information technology in the NHS and taking account of current NHS policy we will discuss this area considering a number of aspects.

These are:

- What type of information or details would be required by the NHS in order to support the development and or implementation of a CDSS to support the prescribing of specialist drugs?
- In your opinion would such a CDSS benefit from being in an “active” form or a “passive” form, and why?
- What would be the cost (if any) of supporting of the implementation of such a CDSS within primary care and GP practices?
- What barriers could there be in either the development or implementation of such a CDSS within general practice and could such barriers be overcome?
- How should such a CDSS be funded if it were to be made available to all GP practices?

- Should or would the NHS fund the development and / or implementation of such a CDSS for use by GPs?

## **Conclusion**

Thank you for your time and I am very grateful for giving me insight into your experience of information technology and the NHS and your views on the potential use of CDSS to support prescribing in general practice. I would like to remind you that if you wish to withdraw from the study you will need to inform the research team within 48 hours.



## Appendix 3.4

**INTERVIEW SCHEDULE**

**Exploratory study to gather the views of key informants in relation to the use of computerised decision support software (CDSS) in UK general practice.**

**CDSS STAKEHOLDER VERSION****Introduction**

Thank you for agreeing to participate in this study which aims to explore the views, perceptions and experiences of individuals in the use of CDSS. I will be grateful if you could confirm that you have seen and read the information sheet and that you have read and signed the consent form. During the interview I will be taking written notes but will also be using a tape recorder to help me write up a transcript. The recording will be destroyed after the completion of my doctorate. Please explain things to me as if I am one of your colleagues. I may ask you for clarification and examples of the topics discussed. Feel free to stop me if you have any questions or need anything explained.

**Background**

Firstly I would like some background information about **yourself and your work** to include:

- What is your current (and / or previous) experience of CDSS e.g. R&D, Sales?
- Describe the current uptake of CDSS within the UK, in particular primary care and general practice
- How does CDSS integrate with general practice computer systems?
- Describe the specific characteristics and design features of the CDSS that you are responsible for and if so could they improved in any way?
- How is the CDSS you are responsible for funded, and are you aware of other funding models in the UK?
- What future developments in CDSS within primary care are you aware of to include specific drugs, therapeutic areas and clinical speciality?

### CDSS: Enablers and Barriers

CDSS is widely available within primary care settings in the UK as computers are now common place in GP practices. The actual use and perceptions of those using CDSS may be influenced by a number of factors. Based on your knowledge and experience in this area we will be discussing this further, consider the following questions:

- What are your experiences of with regards to actual usage and acceptance of CDSS from either end users or purchasers (NHS)?
- How are either end users or purchasers involved in the on-going management of or development of CDSS?
- What are the barriers to implementation of CDSS within primary care that you are aware of and how can these be avoided or removed?

### Potential Area for CDSS Development

In England during 2010 / 11 over 1.6 million prescription items were issued by GPs for specialist drugs at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill. Of this £65 million (26.3%) was spent on the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus. In addition these four drugs accounted for 31.7% of all specialist drugs prescribed, making these the **most frequently issued by GPs in primary care**. As a potential area for development this study will be looking to explore if CDSS could have a role in helping GPs prescribe and manage specialist drugs in primary care. Based on your experience of CDSS, general practice, primary care and taking account of current NHS policy we will discuss this area considering a number of aspects. These are:

- What sort of information or detail would be required in order to develop a CDSS to support the prescribing of specialist drugs?
- In your opinion would the CDSS benefit from being in an “active” form or a “passive” form, and why?
- What would be the cost of developing such a CDSS, and how long would it take?
- What barriers could there be in either the development or implementation of such a CDSS within general practice?
- How should such a CDSS be funded if it were to be made available to all GP practices?

## **Conclusion**

Thank you for your time and I am very grateful that you have given me an insight into your views and perceptions of CDSS. I would like to remind you that if you wish to withdraw from the study you will need to inform the research team within 48 hours.

## Appendix 3.5

**REC Reference: BDM/11/12-82**

Dr Cate Whittlesea  
Institute of Pharmaceutical Sciences  
Room 5.79, 5<sup>th</sup> Floor  
Franklin Wilkins Building  
Kings College London  
Stamford St  
London SE1

Participant Name  
Address

Date: .....

### **An exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.**

We are writing to invite you to take part in a research study that aims to explore the views, perceptions and experiences of individuals involved in the use of CDSS and its potential role in supporting GPs in the use and management of specialist drugs. The key informants involved in this study represent the following four stakeholder groups; NHS secondary care clinicians, NHS management, GPs, representatives from the CDSS industry and expert advisors. The study will involve participants being interviewed by a member of the Research Team for approximately 1 hour. This study has been approved by King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (Reference BDM/11/12-82).

### **Background**

The last 30 years has seen the emergence of Computerised Decision Support Systems (CDSS) to aid diagnosis, dose calculations and more recently to support computerised or electronic prescribing via alerts to warnings on drug interactions, allergies and contraindications. CDSS can function as either "active" whereby it interacts within a host clinical system or "passive" whereby the end user decides when and where to use it. CDSS is widely available within primary care settings in the UK as computers are now common place in GP practices. Developmental experience of CDSS in UK general practice has supported both disease management and therapeutic drug monitoring. In recent years CDSS have been introduced that provide prescribing support with national and locally authored patient safety messages and drug formulary recommendations.

## Specialist Drugs

In recent years there has been a growing trend for some specialised hospital initiated treatments to be managed within primary care, attributed to patient convenience, better risk management, a reduction in secondary care workload (e.g. out-patient appointments) and the transfer out of prescribing expenditure. In England during 2010 / 11 over 1.6 million prescription items were issued by GPs for specialist drugs at a cost of £250 million, 3.13% of the total £7.98 billion national primary care drugs bill. Of this £65 million (26.3%) was spent on the immunosuppressant drugs ciclosporin, mycophenolate, sirolimus and tacrolimus. In addition these four drugs accounted for 31.7% of all specialist drugs prescribed, making these the most frequently issued by GPs in primary care.


The results of the this phase of the study will be used to build and extend the current knowledge base of the research area and to develop a draft operational framework for a potential CDSS to support GPs in the prescribing specialist drugs to include specific clinical standards and end-user features. If you are interested in taking part in this study, please read the attached participant information sheet, and if you wish to participate in this study please complete the attached consent form and return it to the research team in the stamp addressed envelope provided by.... (7 days from the letter date). If you would like any further information about the study before you make the decision about participating, please contact either Narinder Chana (primary contact) by either e-mail ([narinder.chana@kcl.ac.uk](mailto:narinder.chana@kcl.ac.uk)) or telephone (020 331 39310), or Dr Cate Whittlesea via ([cate.whittlesea@kcl.ac.uk](mailto:cate.whittlesea@kcl.ac.uk)) or 020 7848 4796.

Thank you for your time and attention.

Yours faithfully,



Narinder Chana  
(Researcher)



Dr Cate Whittlesea  
(Researcher)



Professor Brendan  
Delaney (Researcher)

## Appendix 3.6

**PARTICIPANT INFORMATION LEAFLET.****Exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.**

We would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

The study intends to build on the current knowledge base of computerised decision support systems (CDSS) in the UK by engaging with key stakeholders and GPs as end user clinicians. This will allow a better understanding of current characteristics of CDSS available and to determine views and perceptions of their use, performance and scope for further development. From this it is intended to develop an operational framework for a novel CDSS, to include functionality and clinical standards to address the needs of GPs in the prescribing and management of specific specialist drugs. This study has been approved by King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (Reference BDM/11/12-82).

**Why have I been chosen to participate?**

A literature review of CDSS and prescribing has formed the basis of this study. This preliminary stage will inform us of key aspects in relation to the research question from those individuals that are actively involved within the field. These individuals represent NHS management, secondary care clinicians, GPs and the CDSS industry.

**Do I have to take part?**

**No.** It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a form giving **informed consent**. If you decide to take part you are still free to withdraw from the study **without giving a**

**reason.** If you do change your mind and decide to withdraw just contact the Research Team to let them know. Please note data can only be withdrawn up to 48 hours after the interview.

#### **What would happen to me if I take part?**

You will be invited to participate in a **confidential** interview with a member of the research team (Narinder Chana). The interviews will take approximately an hour at a convenient date and time. This will be held at a suitable venue that you decide is best for you. With your consent, the interviews will be audio-recorded. All data collected by the research team as part of the study is strictly **confidential**.

#### **What are the possible benefits of taking part?**

Your input will help and inform future developments in the field of medical informatics which will contribute to improving the way patients are treated and managed within primary care. In recent years an increasingly greater number and range of specialist drugs and treatments are being used outside of hospital prescribed for and managed by GPs. It is important that this is done safely and effectively and using CDSS may enhance the prescribing and monitoring of these medicines.

#### **What happens when the research study stops?**

The Research Team is keen to learn of areas where prescribing quality can be improved and will welcome any comments or suggestions in relation to CDSS and the use of specialist drugs. These comments should be directed to Narinder Chana.

#### **What if something goes wrong?**

It is not anticipated that taking part in this exploratory study will cause any pain, discomfort, inconvenience or changes to lifestyle.

#### **Would my taking part in this study be kept confidential?**

All information collected about you during the course of the research study is kept strictly **confidential**. The interviews are confidential and the data collected will be **anonymised** by the researcher. It will NOT be possible to link information used in the research report back to you. Reports and data collected will be stored securely at King's College London.

### **What would happen to the results of the research study?**

Individuals will not be identified in any report or publication. The findings will be shared across the Medicines Management Teams within the Outer North West London Cluster of Primary Care Trusts and the London Primary Care Practice Research Network. The study will be described in the Doctorate in Health Care thesis of Narinder Chana. It is anticipated the results of this study will be published and or presented at a national / international level so all information gained is shared widely. If you would like a copy of any resultant publication, you will be sent one.

### **Who is organising and funding the research?**

The research is being organised by Narinder Chana, and Dr Cate Whittlesea (Institute of Pharmaceutical Sciences, King's College London) in collaboration with Professor Brendan Delaney (Department of Primary Care and General Practice, King's College London). The research team are providing their time and expertise free of charge. Narinder Chana is a Pharmaceutical Adviser at NHS Ealing Primary Care Trust (PCT).

### **Contacts for further information.**

Should you have any further questions, or would like to enquire further please contact Narinder Chana or Cate Whittlesea by either e-mail or phone number between 9am-5pm Monday to Friday.

Narinder Chana: [Narinder.chana@kcl.ac.uk](mailto:Narinder.chana@kcl.ac.uk) 020 331 39310

Cate Whittlesea: [cate.whittlesea@kcl.ac.uk](mailto:cate.whittlesea@kcl.ac.uk) 020 7848 4796

If you are happy to participate in this study, please complete the attached consent form and return it to the research team in the enclosed stamp addressed envelope. If this study has harmed you in any way you can contact King's College London using the details below for further advice and information.

#### **Contact:**

Dr Cate Whittlesea Institute of Pharmaceutical Sciences, Room 5.79, 5th Floor, Franklin Wilkins Building, Kings College London, Stamford St, London SE1

**Thank you for reading this information sheet which is yours to keep.**



## Appendix 3.7

REC Study Number: BDM/11/12-82

<p style="text-align: center;"><b>CONSENT FORM</b></p> <p style="text-align: center;"><b>Exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.</b></p>
---

Research team: Narinder Chana, Dr Cate Whittlesea, Professor Brendan Delaney (King's College London). You are provided with two copies of this consent form; one is to be returned to the research team in the stamped addressed envelope provided, and the other for you to keep.

	PLEASE INITIAL OR TICK IN BOX
1. I have read and understand the participant information leaflet (version 1) for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>
2. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving reason. Furthermore, I understand that I will be able to withdraw my data up to 48 hours after the interview	<input type="checkbox"/>
3. I agree that what I say during the interviews can be used, anonymously in the presentation of the research.	<input type="checkbox"/>
4. I agree and give consent to the interview being audio recorded	<input type="checkbox"/>
5. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998	<input type="checkbox"/>
6. I <b>AGREE</b> , and give <b>INFORMED CONSENT</b> / <b>DO NOT AGREE</b> (delete as appropriate) to take part in the above study	<input type="checkbox"/>

**Please DO / DO NOT (delete as appropriate) send me a report on the results of this study.**

Address for those requesting a report

.....

Name of participant  
Date

Signature

Name of researcher  
Date

Signature

## Appendix 3.8

**REC Reference: BDM11/12-82**

Dr Cate Whittlesea  
Institute of Pharmaceutical Sciences  
Room 5.79, 5<sup>th</sup> Floor  
Franklin Wilkins Building  
Kings College London  
Stamford St  
London SE1

Participant Name  
Address

Date: .....

### **An exploratory study to gather the views of key informants in relation to the use computerised decision support software (CDSS) within UK general practice.**

Thank you for agreeing to take part in this study. We are writing to confirm that we have received your consent form and that Narinder Chana will be contacting you shortly to arrange a suitable date time and venue for your interview. This interview will be confidential and the data collected will be anonymised and it will not be possible to link information used in the research report to you. The interview will be audio-recorded and the recording will be used in order to prepare a transcript. The tape recordings will be destroyed at the end of the study. A number of key aspects in relation to the research study will form the basis of these interviews and will raise specific discussion areas to include:

- Current usage levels of CDSS within UK general practice
- Views and perceptions of end-users (GPs) of the quality and effectiveness of CDSS
- Integration of CDSS with general practice computer systems.
- Current and possible future funding models for CDSS in the UK
- Future developments in CDSS in the UK within primary care to include specific drugs, therapeutic areas and clinical speciality.
- Government health policy and the financial position of the NHS related to CDSS implementation
- Current arrangements in the prescribing and on-going management of specialist drugs including the relationship between hospital specialists and GPs.
- Scope for the development of a CDSS that can support GPs in the prescribing of these drugs

Please do not hesitate to contact us if you have any further queries or require further information about the study. I look forward to speaking to you shortly to arrange your interview.

Thank you for your time and attention.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Narinder Chana', with a stylized flourish at the end.

Narinder Chana  
(Researcher)

A handwritten signature in purple ink, appearing to read 'Cate Whittlesea', with a horizontal line above the last name.

Dr Cate Whittlesea  
(Researcher)

A handwritten signature in black ink, appearing to read 'B.C. Delaney', with a horizontal line under the last name.

Professor Brendan  
Delaney (Researcher)

## Appendix 4.1

### Exploratory study using key informants to investigate the use computerised decision support software (CDSS) within UK general practice. Hierarchical Task Analysis (HTA): Researcher Guide

#### Background Questions

- Obtain some background details about the GP to include, gender, specialty, years since qualification. Ask the GP to briefly describe his / her level of experience of using computers in general practice.
- Observe the way the consultation room is organised, where does the patient sit, where does the GP sit, how does the use of the computer impact on the consultation, can the patient see the computer screen?

#### Building the Task Diagram

- Can you describe the main stages of a typical patient consultation and how you use the computer?
- Can you show me what you look at on the computer and what functions are used?
- How are these functions used and what steps do you have to take to complete these functions?
- If during this consultation you require to issue medication what steps do you have to take, how does the computer take you through this process?
- What sort of functions and features either support or hinder this process e.g. CDSS?
- Describe the above when you need to issue medication outside of a patient consultation?

#### Case Scenario

Please describe what you would do in the following scenario?

- You have received a letter from a hospital to prescribe a “specialist drug” that you are not familiar with for one of your patients. The hospital letter refers to a “shared care protocol” that you need to follow but it is not enclosed. Describe what you would do and how you would use your computer including any specific functions to help you decide whether to prescribe the “specialist drug” or not?

- You have decided to prescribe the “specialist drug”, what steps do you now take in terms of using the computer and any specific features and functions. Would there be any additional tasks that you need to do which would involve the use of the computer and any specific features or functions in the longer term for using this specialist drug in this patient?

## Appendix 4.2

### **PARTICIPANT INFORMATION LEAFLET.**

#### **Exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.**

We would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

#### **What is the purpose of the study?**

The study intends to build on the current knowledge base of computerised decision support systems (CDSS) in the UK by engaging with key stakeholders and GPs as end user clinicians. This will allow a better understanding of current characteristics of CDSS available and to determine views and perceptions of their use, performance and scope for further development. From this it is intended to develop an operational framework for a novel CDSS, to include functionality and clinical standards to address the needs of GPs in the prescribing and management of specific specialist drugs. This study has been approved by King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (Reference BDM/11/12-82).

#### **Why have I been chosen to participate?**

A literature review of CDSS and prescribing has formed the basis of this study. In addition an initial phase of this study has been completed which involved interviews with key individuals that represent NHS management, secondary care clinicians, GPs and the CDSS industry. This final phase is an observational study that will analyse and detail how GPs use computers and computing software such as CDSS both during and outside a patient consultation.

### Do I have to take part?

**No.** It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a form giving **informed consent**. If you decide to take part you are still free to withdraw from the study **without giving a reason**. If you do change your mind and decide to withdraw just contact the Research Team to let them know. Please note data can only be withdrawn up to 48 hours after the study.

### What would happen to me if I take part?

You will be invited to participate in a **confidential** observational study with a member of the research team (Narinder Chana). This study will take approximately an hour at a convenient date and time and will need to take place within your GP practice consultation room. The study will involve the researcher asking you to demonstrate how the computer and computer software is used both during and after patient consultations. In addition the researcher will ask you about usage in a number of clinical scenarios. All data collected by the research team as part of the study is strictly **confidential**.

### What are the possible benefits of taking part?

Your input will help and inform future developments in the field of medical informatics which will contribute to improving the way patients are treated and managed within primary care. In recent years an increasingly greater number and range of specialist drugs and treatments are being used outside of hospital prescribed for and managed by GPs. It is important that this is done safely and effectively and using CDSS may enhance the prescribing and monitoring of these medicines.

### What happens when the research study stops?

The Research Team is keen to learn of areas where prescribing quality can be improved and will welcome any comments or suggestions in relation to CDSS and the use of specialist drugs. These comments should be directed to Narinder Chana.

### What if something goes wrong?

It is not anticipated that taking part in this exploratory study will cause any pain, discomfort, inconvenience or changes to lifestyle

### **Would my taking part in this study be kept confidential?**

All information collected from you during the course of this research study is will be anonymised and kept strictly **confidential**. It will NOT be possible to link information used in the research report back to you. Reports and data collected will be stored securely at King's College London.

### **What would happen to the results of the research study?**

Individuals will not be identified in any report or publication. The findings will be shared across the Medicines Management Teams within the North West London Clinical Commissioning Groups (CCGs) and the London Primary Care Practice Research Network. The study will be described in the Doctorate in Health Care thesis of Narinder Chana. It is anticipated the results of this study will be published and or presented at a national / international level so all information gained is shared widely. If you would like a copy of any resultant publication, you will be sent one.

### **Who is organising and funding the research?**

The research is being organised by Narinder Chana, and Dr Cate Whittlesea (Institute of Pharmaceutical Sciences, King's College London) in collaboration with Professor Brendan Delaney (Department of Primary Care and General Practice, King's College London). The research team are providing their time and expertise free of charge. Narinder Chana is a Pharmaceutical Adviser at NHS Ealing Clinical Commissioning Group (CCG). .

### **Contacts for further information.**

Should you have any further questions, or would like to enquire further please contact Narinder Chana or Cate Whittlesea by either e-mail or phone number between 9am-5pm Monday to Friday.

Narinder Chana: [Narinder.chana@kcl.ac.uk](mailto:Narinder.chana@kcl.ac.uk) 020 331 39310

Cate Whittlesea: [cate.whittlesea@kcl.ac.uk](mailto:cate.whittlesea@kcl.ac.uk) 020 7848 4796

If you are happy to participate in this study, please complete the attached consent form and return it to the research team in the enclosed stamp addressed envelope. If this study has harmed you in any way you can contact King's College London using the details below for further advice and information.



**Contact:**

Dr Cate Whittlesea Institute of Pharmaceutical Sciences, Room 5.79, 5th Floor, Franklin Wilkins Building, Kings College London, Stamford St, London SE1

**Thank you for reading this information sheet which is yours to keep.**

## Appendix 4.3

REC Study Number: BDM/11/12-82

<b>CONSENT FORM</b> <b>Exploratory study using key informants to investigate the use of computerised decision support software (CDSS) within UK general practice.</b>
--

Research team: Narinder Chana, Dr Cate Whittlesea, Professor Brendan Delaney (King's College London). You are provided with two copies of this consent form; one is to be returned to the research team in the stamped addressed envelope provided, and the other for you to keep.

	<i>PLEASE INITIAL OR TICK IN BOX</i>
1. I have read and understand the participant information leaflet (Version 2) for the above study and have had the opportunity to ask questions.	<input style="width: 80px; height: 25px;" type="text"/>
2. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving reason. Furthermore, I understand that I will be able to withdraw my data up to 48 hours after the study.	<input style="width: 80px; height: 25px;" type="text"/>
3. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998'	<input style="width: 80px; height: 25px;" type="text"/>
4. I <b>AGREE</b> , and give <b>INFORMED CONSENT</b> / <b>DO NOT AGREE</b> (delete as appropriate) to take part in the above study	<input style="width: 80px; height: 25px;" type="text"/>

**Please DO / DO NOT (delete as appropriate) send me a report on the results of this study.**

Address \_\_\_\_\_ for \_\_\_\_\_ those \_\_\_\_\_ requesting \_\_\_\_\_ a \_\_\_\_\_ research report.....

Name of participant  
Date

Signature

.....  
Name of researcher  
Date

.....  
Signature